Travail™

Intra Uterine Insemination Kit

MEDICAL
INTERVENTIONS

Travail-H medium was developed for in vitro procedures involving the sperm washing, culture and swim-up for IUI. It is an improved formula of HBSS provided in the form of 10X concentration.

COMPOSITION:

- Calcium Chloride
- Magnesium Sulphate
- Potassium Chloride
- Potassium Phosphate Mono basic
- Sodium Bicarbonate
- D- Glucose
- Di-sodium Hydrogen Phosphate

Product Specifications:

TEST	SPECIFICATIONS
Appearance (Turbidity)	Clear
Appearance (Form)	Solution
pH at 10X	5.7 – 6.1
pH at 1X with NaHCO3	7.0 – 7.6
Osmolarity at 1X with NaHCO3	266-294 mOs/Kg
Salt Toxicity Test	Pass
Cell Line	Cell Line- Cell Types

Sterility	Pass
Endotoxin at 1X	<= 1 EU/ml
Glucose Concentration	9.0 – 11.0 g/l

STERILE A
Sterilized using aseptic processing techniques.

PRE-USE CHECK
- Do not use the product if any signs of microbial contamination are noticed
- Do not use if any discoloration, turbidity or precipitation noticed
- Do not use the product if seal of the container is defect or opened upon delivery

INSTRUCTIONS FOR USE:
- Dilute Travail-H swim-up media with 1.8ml of w.f.i. (water for injection)
- Once reconstituted, use on same day. Do not store
- Before use warm Travail-H swim-up media to 37^0C at least 30 mins.

STORAGE & STABILITY:
- Store at ambient temperature
- Do not freeze or expose to temperatures higher than 39^0C
- The product is stable until the expiration date shown on the label

The mission of MEDICAL INTERVENTIONS is to make the treatment of infertility accessible to every infertile patient through the intervention of its simple, affordable, and successful tecnhnologies. MEDICAL INTERVENTIONS organises workshops to train physicians & laboratory personal our technologies to complete this mission. Travail – H procedure combined with ovarian stimulation and ovulation management will make the IUI process easier and less expensive with satisfactory results.

This manual developed to help physicians and lab personal while performing the Travail - H procedures. The manual contains precious information regarding the protocols, Travail - H Procedure (including a model of consent form), suggestions for quality controls, quality insurance, safety rules to observe and several other crucial steps.

We hope this INTERVENTION in the field of reproductive medicine becomes one of your routine practices of treating infertile patients at earliest. Our MOTTO is to serve healthcare professionals to offer their treatments affordable so that patients GET IT TREATED EARLY.

With Best Wishes
Medical Interventions Private Limited

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1. PRE-IUI SCREENING

I) PURPOSE

Patients who are diagnosed with "Infertility," must be evaluated to determine the cause of infertility and its best treatment. The diagnosis can be made utilizing tests previously performed if the tests are sufficiently documented and are performed within the last year. The infertility work up can be complimented by doing additional testing as necessary.

II) INDICATIONS FOR THE TRAVAIL-H PROCEDURE

The Travail – H procedure is a variation sperm preparation for an IUI.

The indications for Travail-H are very similar to those of IVF. Severe cases of male infertility & Tubal factor, however, cannot appropriately be treated by Travail - H and should be treated by other procedures like IVF (In-Vitro Fertilization) & ICSI (Intra Cytoplasmic Sperm Injection).

Travail - H is indicated for:

1. Unexplained Infertility
2. Mild Male Factor
3. Severe pelvic adhesions
4. Endometriosis and
5. Ovulation Dysfunction.

Unexplained infertility

When no cause of infertility is found after a thorough evaluation of the couple, the infertility is classified as unexplained. Possible explanations for the diagnosis of "unexplained" include,

sperm not being able to reach into the fallopian tube, or sperm not being able to fertilize the egg. Even though the exact cause is unclear, Travail – H is often very successful in overcoming these potential problems. Within the current path of care, couples with unexplained infertility first undergo treatment with infertility drugs and combination of IUI with Travail – H.

Mild Male Factor

Sperm abnormalities are another common cause of infertility including abnormally low sperm count, low sperm motility, and low percentage of normal sperm forms. Travail – H may be used to over come mild cases of sperm abnormalities because the sperm can be concentrated allowing fertilization to occur inside the fallopian tubes. However, most severe cases (total motile sperm count less than 500,000 per ml after processing) require further intervention, most commonly ICSI. ICSI is performed by an experienced embryologist in an IVF center.

Severe Pelvic Adhesion's, Endometriosis

Severe pelvic adhesions can be a result of severe endometriosis, previous surgery or other previous inflammatory processes. The tubes may or may not have been damaged, but preventing the egg not coming in contact with sperm. Travail - H is an ideal way to overcome these problems.

Ovulatory Dysfunction

Ovulatory dysfunction is a common cause of infertility which is often treated with ovulation inducing medications. However,it is not possible to predict how patients will respond to such

ovarian stimulation. When too many follicles are produced, proceeding with an IUI cycle could result in multiple pregnancies. So while stimulating always better to start with low doses.

III) INFERTILITY EVALUATION

Counseling of a patient by the physician and his or her staff at the initial consultation and during all steps of infertility treatment is one of the most important aspects of care. Counseling is also important in the post treatment phase when it is possible that the patient will not become pregnant. During the initial consultation, it is important to determine the diagnosis for infertility. This will establish if the patient is a good candidate for Travail – H. The diagnosis can be made utilizing tests previously performed if the tests are sufficiently documented and are performed within the last year. The infertility work up can be complimented by doing additional testing as necessary.

Obtain a full clinical history and perform a physical examination for both partners.

IV) MAXIMIZING OUTCOMES WITH THE TRAVAIL – H PROCEDURE

Conditions favoring a Successful Travail - H procedure:

- Unexplained infertility with unsuccessful attempts in achieving pregnancy through timed intercourse or medication.
- Normal sperm count and motility.
- Normal uterine cavity.

- Normal baseline ultrasound with adequate number of primary follicles present.
- Normal FSH and E2 on Day 3.
- Age of the female patient is < 35 years old.

Factors Reducing the Chance for Success of an Travail – H procedure:

1. If previous attempts of medical management or natural intercourse resulted in no conception and advancing maternal age.
2. Male patient who has difficulty producing a semen sample.
3. Very low sperm count, low percentages of motility and morphology.
4. Age of female patient (moderately if the age >37 years old; markedly if age >40).
5. Borderline or elevated E2 or FSH on Day 3 or low blood inhibin levels.
6. Poor natural ovarian response
7. Patient with PCO syndrome (Poly cystic Ovary).
8. Hydrosalpinx (reduces the chance of successful implantation by 50% and also increases miscarriage rate).
9. Anatomic difficulties.
10. Cervical Stenosis
11. Uterine abnormalities or deformities.
12. Obesity.
13. Smoking.
14. Calcium channel blocking agents.

V) TRAVAIL – H PATIENT ORIENTATION

STEP1: Orientation Program

Infertile couples undergoing an Travail – H procedure will have to go through several weeks of tests and treatment. Accordingly, we recommend that the physician establish patient orientation sessions to educate the couples and to reduce their stress. Topics included in the orientation sessions should include injection training for drugs used in ovarian stimulation, how to obtain medications and time requirements related to the Travail - H cycle.

STEP 2: Consent Form

Prior to initiation of treatment, the patient must execute the consent form in the presence of the physician or authorized individual when possible. A sample of a consent form that can be used as a reference is included in the attachment section. This consent form is only a sample and can be modified based on the rules and regulations in place in your country.

2. CLINICAL EVALUATION: FEMALE

I) INTRODUCTION

Infertility can be defined as the inability to achieve pregnancy after one year of unprotected intercourse. The basic infertility evaluation involves careful meticulous assessment of all phases of the reproductive system including the potential for ovulation, conception, implantation, continued pregnancy and delivery. Since infertility affects both women and men it is imperative to have both the male and female undergo an investigation.

II) FEMALE INVESTIGATION

History and Physical

The female infertility evaluation should start prior to the standard twelve month time frame of unprotected intercourse when a women is over the age of 35, has a history of irregular menstruation or known pelvic or tubal pathology or a partner that is undergoing infertility treatment for a male factor. Often a very in depth questionnaire is helpful for patients to fill out prior to seeing the clinician and beginning the evaluation process.

The initial evaluation of the female should begin with a history and physical exam. This history should include:

1. Complete pregnancy history with special attention to any abnormalities
   a) Age at menstruation and cycle regularity
   b) Duration of current fertility attempts

c) History of birth control and frequency of sexual intercourse
d) Medical, surgical and family history (particularly DES exposure and history of STD)

1. Medications and allergies
2. Occupational/environmental exposures
   e) Life style choices regarding smoking, alcohol and recreational drugs
   f) Symptoms of thyroid disease, pelvic ab normalities, galactorrhea, hirsutism and painful intercourse

The physical exam is also important at this time and should include:

1. Examination of the thyroid for any swelling or nodules
2. Thorough breast exam for evidence of discharge
3. Pelvic exam to assess the uterus, cervix and vagina
   a) Height and weight
   b) Blood pressure, pulse and respiration

Diagnostic Evaluation

Ovulatory Function

The assessment of ovulation is the first step in providing a systematic evaluation of female reproduction. Ovulatory dysfunction accounts for 40% of infertility in women. Ovulation can be assessed by obtaining an in depth menstrual history and using the following diagnostic tools.

1. Basal body temperature - A biphasic result will show an increase in temperature for 11 days

2. Serum progesterone level - A serum progesterone level of 10ng/ml will indicate ovulation
3. LH kit urinary test - A positive test indicates the presence of LH in the urine
4. Vaginal ultrasound - Will assess the developing and ovulated follicle
5. Endometrial biopsy - Evaluates endometrial response to circulating serum progesterone

In the presence of irregular menses it can also be beneficial to also investigate the levels of TSH, prolactin and FSH. Clomiphene challenge tests can also be used in patients over thirty five and those patients with irregular menses to assess ovarian reserve.

Uterine / Tubal Function

Careful history regarding any type of prior pelvic abnormalities is scrucial at this time since many pelvic infections are asymptomatic and can lead to impaired tubal function.

Tubal disease accounts for 40% of female infertility and several diagnostic tools can be used to evaluate the pelvis. The sequence regarding the use of these tools is dependent on the history and age of the patient.

HSG /Hystero salpingogram - X-ray which assesses the internal uterine cavity for abnormalities and tubal patency.

Sono hysterogram - Ultrasound with the injection of sterile saline or water to evaluate the uterine cavity

Hysteroscopy - Direct visualization of the uterine cavity for abnormalities Ultrasound - Evaluates pelvic structures: uterus, ovaries and endometrium

Laparoscopy - Direct visualization of the entire pelvis which can evaluate the pelvic anatomy for evidence of disease (endometriosis, pelvic adhesions) and damage to pelvic organs (fallopian tubes, ovaries)

3. CLINICAL EVALUATION: MALE

I) MALE INVESTIGATION

History: Similar to the female evaluation the male should have an in depth history obtained prior to any treatment modalities. This history should include the following

1. Frequency and timing of intercourse
2. Duration of infertility and prior fertility
3. Medical, surgical and family history
4. Childhood illnesses
5. Sexual history including assessment of STD's Occupational/environmental exposures
6. Life style choices regarding smoking, alcohol and recreational drugs
7. Medications and allergies.

At the time of initial evaluation the male should have two semen analysis performed preferably a month apart.

Normal Parameters Below (As defined by the World Health Organization, WHO):

Ejaculate Volume	: 1.5- 3.0 ml
pH	: >7
Sperm concentration	: >20 million/ml
Total sperm number	: >40 million/ejaculate
Percent motility	: >50 %
Forward progression	: >2 (scale 0-4)
Normal morphology	: >30% (1992), >4% (Kruger)
Sperm agglutination	: <2 (scale 0-3)
Viscosity	: <3 (scale 0-4)

In the situation where the semen analysis is normal the male can begin fertility treatment without further investigation. Should the semen analysis be abnormal the male should be referred to an urologist or physician that specializes in reproductive medicine for continued evaluation. This full evaluation may consist of the following to determine the male factor involved:

- In depth medical history
- Physical exam
- Semen analysis
- Hormone evaluation
- Post ejaculatory urinalysis
- Ultrasonography (transrectal and /or scrotal)
  - Specialized clinical tests on semen and sperm
- Genetic screening

4. CYCLE STIMULATION PROTOCOLS OVULATION PROTOCOLS AND MONITORING

I) PURPOSE

Several protocols are available to monitor follicle development. Five protocols are described here:

1. Modified natural cycle
2. Letrozol or clomiphene citrate (CC) alone
3. Letrozol or CC with human gonadotropins
4. Human gonadotropins (mild stimulation)
5. Oral contraceptive preceding ovarian stimulation

These protocols use no stimulation or a mild stimulation for the purpose of recruiting only a few follicles. This is in contrast to the usual IVF cycle where stimulation is designed to maximize the number of eggs obtained.

II) THE PROTOCOLS

A) Modifed Natural Cycle Protocol using Indomethacin or GnRH Antagonist

Overview: The natural cycle protocol is most suitable for patients who have normal menstrual cycles and who object to taking medication because they are concerned about side effects or would like to avoid the creation of multiple embryos or the risk of multiple pregnancies.

Advantages: None or a small quantity of medication, low cost.

Disadvantages: Lower pregnancy rate and higher risk of cycle cancellation than a mild stimulated cycle. These disadvantages can be prevented if indomethacin or antagonists of GnRH are used.

STEP1: Monitoring

1. Day one of the cycle is the start of menstruation.

On Day 8

2. Start monitoring the cycle on day 8 of the woman's regular menstrual cycle.
3. Do a pelvic ultrasound (USG) to determine follicle size. Determine levels of serum E2(estradiol) and LH (luteinizing hormone) through serial testing.

If E2 is $\geq$ 150pg /ml per mature follicle (over 15 mm in diameter), repeat E2 and LH the next day.

If E2 is < 150 pg /ml and the leading follicle is < 15 mm, repeat ultrasound and E2 and LH measurements 2 days later.

STEP2: Procedure Timing

The timing of the retrieval is based on either the onset of the LH surge or is scheduled after hCG administration.

LH Surge:

1. To prevent premature ovulation, Indomethacin 150mg/ day (50mg x 3) starting on day 8 of the cycle has been

used successfully until the evening preceding the IUI. To prevent the LH surge, GnRH antagonist may also be used successfully as described below in Protocol D. But antagonists are very expensive and do not seem to be a solution for a low cost stimulation protocol.

2. If a LH surge occurs, IUI can be done programmed on the LH surge.
3. If LH level doubles over baseline value with E2 greater than or equal to 150 pg / ml, plan to do the IUI provided LH levels have continued to rise.
4. If the next morning, the LH level is greater than 60 IU/ml with a dramatic drop in the E2 level (over 50% of the previous value) indicating the down ward limb of the LH peak, do the IUI asap.

hCG Administration: Use an hCG injection (5,000 IU) when no LH surge occurred and schedule an IUI 36 hours later.

Cancellation Criteria

- Premature LH surge
- Poor follicular development

B) Clomiphene Citrate Protocol

Overview: This protocol has been modified from the Trouns on publication (5).

Advantages: Easy instructions for the patient to follow, minimal monitoring required. In general, 1 to 5 mature follicles are likely to be grown.

Ovarian hyper-stimulation syndrome (OHSS) is extremely rare.

Disadvantages: The use of Clomiphene Citrate (CC) may result in a thin endometrium (<7 mm) from its anti - estrogenic

STEP1: Stimulation and Monitoring
Day one of the cycle is the start of menstruation.

On Day 3
1. Give Clomiphene Citrate 100 mg (PO) for 5 days beginning on day 3 of the cycle
2. Perform a baseline, pelvic ultrasound. If any abnormality is detected through the ultra sound, reevaluate whether to proceed or to postpone the procedure.

On Day 8
1. Perform pelvic ultrasound and/or measure E2 and LH and repeat these tests every day once the lead follicle is $\geq$ 15 mm or every other day if the size is < 15 mm.
2. Start Indomethacin 150mg /day (50mg x3, PO) to block the ovulation and give it until the evening preceding the IUI. An antagonist of GnRH (Antagon or Cetrotide) can also be used to suppress the LH surge (measurements of LH, E2 and progesterone and ultrasound the next morning will confirm pituitary suppression).

An average of 3 ultrasound exams and/or 8 blood assays typically precede the IUI.

STEP 2: Procedure Timing
hCG administration
Inject hCG (10,000 IU) when the following occur:
1. dominant follicle is ≥18 mm in mean diameter
2. E2 level is over 250 pg/ml
3. LH remains as baseline

Perform IUI 36 hours after hCG injection.

Cancellation Criteria
1. Premature Ovulation
2. Premature LH surge
3. Endometrium < 7 mm
4. Poor follicular development
5. Numerous follicles developing (over 10)

C) CC and Gonadotropins Protocol.
Overview: This protocol has been modified from the Trounson publication (6).

Advantages: Easy instructions for the patient to follow, minimal monitoring required. In general, 1 to 5 mature follicles are likely to be grown. OHSS is rare.

Disadvantages: The use of CC may result in a thin endometrium (<7 mm) from its anti - estrogenic and may be detrimental to embryo implantation. The addition of gonadotropins increases the cost of the protocol

STEP1: Stimulation and Monitoring
Day one of the cycle is the start of menstruation.

On Day 3

1. Perform a baseline pelvic ultrasound. If any abnormalities are detected through the ultrasound, reevaluate whether to proceed or to postpone the procedure.
2. Give Clomiphene Citrate 100 mg (PO) for 5 days beginning on day 3 of the cycle.

On Day 5

1. Add Gonadotropin 75 units every other day beginning on Day 5.

On Day 8

1. Perform pelvic ultrasound and/or measure E2 and LH.
2. Start Indomethacin 150mg /day (50mg x3, PO) to block the ovulation and give it until the evening preceding the IUI. A single dose of 3 mg of GnRH antagonist (9) an antagonist of GnRH (Antagon or Cetrotide) can also be used to suppress LH surge (measurements of LH, E2 and progesterone and Ultrasound the next morning will confirm pituitary suppression).
   The purpose of administering 3 mg of GnRH agonist is to suppress LH for 4 days.
   Alternatively, one can give the patient a daily morning dose of 0.250mg GnRH antagonist (10).
3. Repeat LH, E2 every day once the lead follicle is $\geq$ 15mm or every otherday if the size is <15mm.

An average of 8 blood assays and 3 ultrasound exams typically precede the IUI.

STEP2: Procedure Timing
hCG administration

1. Inject hCG (10,000 IU) when the following occur:
2. Dominant follicle is $\geq$ 18 mm in mean diameter
3. E2 level is over 150 pg/ml/per mature follicle (over 15mm)
4. LH remains as baseline.

Do the IUI 36 hours after hCG injection.

Cancellation Criteria

1. Poor responders with poor follicle development
2. Premature ovulation
3. Premature LH surge
4. Endometrium < 7 mm
5. E2 level > 2,500 pg/ml

D) Mild Ovarian Stimulation Protocol Using Human Gonadotropins Alone

Overview: The protocol recommended below combines a low dose of human gonadotropin with the addition of indomethacin to prevent premature ovulation. To prevent the LH surge, GnRH antagonist has also been used successfully (8).

Advantages: The use of Indomethacin 150mg/day has been used successfully used to block the ovulation. The use of a GnRH antagonist virtually eliminates the risk of cycle cancellation due to a premature LH surge. Doses of human gonadotropin needed are significantly lower than the doses used with an agonist. Incidence of severe

ovarian hyperstimulation requiring hospitalization is also dramatically reduced. Moreover, antagonists are generally well-tolerated.

Disadvantages: Mild side effects including light and transitory cutaneous reactions at the site of injection. Additional expense related to the monitoring of the protocol, the use of more gonadotropins and the cost of the GnRH antagonist.

STEP1: Stimulation and Monitoring

Day one of the cycle is the start of menstruation.

On Day 3

1. Give one ampoule of human gonadotropin (75 IU HMG or 75 IU FSH) per day until day 7. At this time, human gonadotropin may be increased to 150 IU per day if the E2 level is less than 200 pg/ml.

On Day 8

1. Perform pelvic ultrasound and/or measure E2 and LH.
2. Start Indomethacin 150mg /day (50mg x3, PO) to block the ovulation give it until the evening preceding the IUI. A single dose of 3 mg of an antagonist of GnRH (9) can also be used to attempt to suppress the LH surge when the dominant follicle size is > 12 mm and /or E2 reaches 400 pg/ml (ultra sound the next morning and /or measure ments of LH, E2 and progesterone will confirm pituitary suppression).The purpose of administering 3 mg of GnRH agonist is to suppress LH for 4 days. Alternatively, one can

give the patient a daily morning dose of 0.250mg GnRH antagonist (10).
3. Repeat ultrasound and /or measurements of LH, E2 and progesterone every day
4. Daily dosing of human gonadotropins continues until the day of the hCG injection. Do not decrease the dose of FSH/HMG after starting antagonist, maintain it or if necessary increase.

STEP2: Procedure Timing
hCG Administration
Inject hCG (10,000 IU) when the following occur
1. Dominant follicle is $\geq$ 18 mm in mean diameter
2. E2 level is over 250 pg/ml
3. LH remains as baseline

Perform IUI 36 hours after hCG injection.

Cancellation Criteria
1. Poor responders with poor follicle develop ment. Premature LH surge on Day 8.
2. E2 level > 2,500 pg / ml, due to the risk of hyper stimulation with numerous follicles.

E. Pre - treatment with Oral Contraceptive followed by Ovarian Stimulation
Overview: This protocol has been developed by Dr. Elkin Lucina (CECOLFES, Columbia) and used successfully with the Travail – H procedure.

Advantages: A period of anovulation induced by oral contraceptives before ovarian stimulation has shown improvement in IUI pregnancy rates. The ovarian quiescence created by the contraceptive pills enhances the pregnancy po-

tential of the mature oocytes recruited during the following stimulated cycle. It also reduces the chance that the patient will have an ovarian cyst at the start of the cycle. Moreover, it allows timing the start of the cycle and the estimated day of egg retrieval. Oral contraceptives administration can be used preceding stimulation with either clomiphene citrate or gonadotropins.

Disadvantages: Risks associated with taking oral contraceptives. Need generally higher doses of Gonadotropins due to the ovarian quiescence created by oral contraceptives.

STEP1: Anovulation by OralContraception

1. Place patients on monophasic low dose of oral contraceptive pills (OCP) continuously for 21 days, 22 days but no more.
2. Before stopping the oral contraceptive pills, perform an ultrasound to check for the absence of cysts (no cyst > 10 mm).
3. Give estradiol (2mg, 3 times a day) for 3 days from D21 or D22 and wait for bleeding. Give antibiotics at the same time to prepare the vaginal cavity

STEP2: Stimulation and Monitoring

Day one of the cycle equals the first day of bleeding (not spotting).

1. On Day 3 (D3), clomiphene citrate (CC) 100 mg for 5 days (D7).
2. Start hMG or FSH (75 IU a day) on Day3 like CC or Letrozol and continue for 5 to 7 days without increasing the dose. The dose of hMG can be increased to 150 IU a day if low responder.

3. When the leading follicle reaches 14 to15 mm (D8 to D10), give Indomethacin (50 mg, 3 times a day) until the evening preceding the IUI. The Indomethacin will prevent a premature ovulation.
4. Monitor as previously described

STEP3: hCG Administration

1. Inject hCG (10,000 IU) when:
2. Leading follicle $\geq$ 17-18mm
3. E2 over 300 pg/ml
4. Endometrium thickness > 7mm

STEP4: Procedure Timing

Do the IUI 36 hours after hCG injection.

Cancellation Criteria

1. Poor patient compliance
2. Premature LH surge
3. Endometrium < 7 mm
4. Poor follicular development
5. E2 level > 2,500 pg / ml, due to the risk of hyper stimulation with numerous follicles.

III) LUTEAL PHASE SUPPORT

The effectiveness of luteal phase support has been widely discussed and is still controversial. However most ART programs prescribe progesterone for luteal phase support as some patients may not produce adequate amounts of progesterone after the procedure.

Traditionally, luteal phase support is given to the patient by progesterone in oil 50 mg (IM) daily. Vaginal suppositories may be used 72hrs post IUI. Luteal phase support by progesterone

is usually continued until the 10th week of pregnancy when the placenta takes over progesterone secretion.

In the protocols developed for Travail - H using the natural cycle or a mild stimulation, luteal phase support by hCG can be used as a substitute for the progesterone supplementation as long as the E2 levels do not exceed 800 pg/ml.

Up to the result of the β hCG. If positive continue the treatment up to 10 weeks otherwise discontinue the progesterone support.

In the last protocol offered by the Dr Elkin Lucina the luteal phase support is composed of:

- Estradiol, 2 to 4mg a day given just after the retrieval until the first β hCG.
- Progesterone 600 mg a day, given vaginally, started after the IUI until the first β hCG.

5. SPERM PREPARATION

I) PURPOSE

The purpose of the procedure is to eliminate seminal fluid and increase the concentration of motile sperm. The two most frequently used techniques are:

"Swim up" Technique: Sperm are first washed with a saline solution and then the motile spermatozoa migrate into culture medium layered over the sperm pellet separating motile sperm from immotile sperm.

In a cycle using the TRAVAIL - H procedure the sperm preparation procedure takes

place before OVULATION, so the oocytes can be inseminated almost immediately after the ovulation in the fallopian tubes.

II) SPERM COLLECTION

1. Sperm should be collected 1- 1.5 hour(s) prior to egg retrieval.

Note: Sperm had to be prepared before ovulation in the T procedure as the oocytes are inseminated immediately after ovulation in the fallopian tubes.

1. Provide patient with instructions prior to appointment. See included Patient instructions in the attachment section.
2. Bring male patient to the “sperm collection room”. See included information on room set-up, cleaning and maintenance in the attachment section.

Note: All specimen containers used for collection of sperm should be sterilized through gamma radiations and not by any chemical /gas method which can be toxic to the sperm ...particularly .... Ethylene oxide

If sterilized by ethylene oxide and no other container is available, rinse twice the container with saline solution before sperm collection. Inform the patient of potential saline solution residues.

III) RECEIPT AND HANDLING OF SAMPLE

After receipt and verification of the correct identity of the sample, fill out the TRAVAIL - H Results Form with all the following information:

1. Patient’s last name, first name, date of birth,

partner's last name, first name, date of birth
2. Number of days of abstinence
3. Method of collection
4. Type of container (only reported if different from the one generally used for sperm collection)
5. Time of specimen collection, time and analysis
6. Collection done alone or with the partner, at home or at the laboratory
7. Any collection or transport problem
8. Abnormalities of liquefaction
9. ID number is recommended to avoid any identification error. Keep this ID number with the sample during every manipulation. It is an essential element for correctly identifying the patient and the couple.

When the sample is collected for Travail - H the patient should sign and date for release of the sperm sample on the Sperm Sample Release Form included in the attachment section. The person receiving the sample should sign as a witness.

Note: Check carefully to be sure that the name, date and I.D. number are the same on the T Results Form and container containing the sample.

Warning: Use protective barriers (e.g. gloves, glasses) when working with exposed biologic materials.

IV) CRITERIA FOR SPECIMEN REJECTION

A. Container for Collection

If a wrong container (cleaned but non sterile) has been used for collection or if the container is broken and the sample is leaking, reject the sample because the risk of contaminating the oocytes is extremely high. Another sample should be collected in an appropriate container.

B. Insufficient Sperm Volume or Motility

Low volume (less than 0.5 ml) is frequently the result of a loss of the first fraction of the ejaculation during sperm collection which contains the most sperm. Therefore, observe a drop of 10µl under the microscope to confirm the absence of sperm. In rare occasions, a normal sperm concentration may be observed. In this case, keep the sample and process it. However, a second sample collection is often needed.

If there is no motility, reject the sample. The reason for the absence of motility should be analyzed with the patient so corrective action can be instituted during the second specimen collection. Residues of soap, use of lubricants, and inappropriate containers (collection at home), and use of condoms containing spermicidal substances could all cause lack of sperm motility.

If the sample is rejected, record the reason for rejection and corrective action suggested on the T Results Form in comments section. File an incident report including the reason for rejection and the outcome to avoid re occurrence of the problem. If the second sample still shows

no motility, inform the patient and cancel the egg retrieval.

Note: Sometimes due to an extremely low motile sperm concentration, even after processing two sperm collections, it is necessary to use a fraction of the pellet for the insemination. This will complement the low sperm concentration in the collected supernatant and allow the procedure to be performed. If this extremely low sperm concentration was not accidental, refer the patient to an IVF center for ICSI evaluation.

V) Travail - H Kit

1. Device for Swim-up
2. Travail-H Swim-up media
3. Sterile IUI Catheter
4. Sterile Syringes

Note: Record each lot number and expiration date on the Travail - H Results Form. Pre - warm device with media soon after reconstitution before use, first at room temperature and then in the incubator for at least 1 hour.

VI) MATERIALS AND INSTRUMENTATION

Disposable instruments:

1. Sterile Travail - H swim-up Device
2. Sterile specimen container 4 oz polypropylene individually wrapped for sperm collection
3. Sterile 1cc syringes
4. Sterile IUI catheter
5. Counting chamber (or hemocytometer – see below or Makler cell)

6. Microscope slides 1 mm
7. Cover glass 22x22mm

Non-disposable instruments:

1. Vertical laminar flow hood (optional)
2. Light microscope
3. Makler chamber or Hemocytometer im proved Newbauer (This is an alternative to the disposable counting chamber).

NOTE: If a non-disposable hemocytometer is used, quality control with microspheres is recommended for accuracy

VII) QUALITY CONTROL

1. Check temperatures of the refrigerator and heating block daily using thermometers. Record temperatures on specials forms posted on or near the equipment.
2. Clean work benches, centrifuge, and micro scope with alcohol 70 % and rinse abundantly with water when contaminated with body fluids.
3. Carry out all procedures under the sterile laminar flow hood.
4. Read the sperm concentration and motility twice and average the two values for the final result.
5. Review forms with the Travail - H results (daily and at the monthly Quality Control meeting by the Medical Director and staff).
6. Calibrate laminar flow hood (if used), adjust able volume pipettes, and centrifuge at least once a year by a bio engineering company. Calibrate microscope when needed.

VIII) SEMEN ANALYSIS

Immediately after specimen collection, place the semen sample in the heating block at 37°C and leave for 15-20 minutes for liquefaction. After liquefaction, thoroughly mix the sample by an up and down movement using an adjustable volume pipette (1 ml) with a sterile tip.

A. Sample Volume

Determine the approximate sample volume using the 1ml pipette. Record results on the Travail - H Results Form.

B. Sample Abnormalities

Report any sample abnormalities in the comments section of the Travail - H Results Form. For example: gelatinous clumps, hyper viscosity of the sample, erythrocytes, or indications of contamination.

C. Sperm Motility

Observe the percentage of motile sperm in the sperm sample. This can be done on a 10 µl drop of sperm sample placed between a slide and a cover slip. A total of at least 100 spermatozoa should be observed in approximately 5 different fields (i.e. on average 20 spermatozoa per field) to determine the motility percentage. This should be conducted in duplicate and the first number determined by averaging the two values. Record the results on the Travail - H Results form.

Note: Since motility is temperature dependent, a standard room temperature of between 20° and 26° C (temperature of the work area)

should be established for assessment of sperm motility. It is recommended to record the temperature of the room on the Room Temperature log (appended).

D. Sperm Concentration

Using an adjustable volume pipette (200 µl) with appropriate tip, mix the sample by gently pulling it in and out of the pipette. Transferapproximately 8 to 10µl of the sperm suspension onto a disposable sperm counting chamber or a hemocytometer taking care to minimize the presence of any cell clumps. After a few minutes, place the counting chamber or hemocytometer under the microscope (objective 40x) and determine the motile sperm concentration by counting the number of spermatozoa in 5 squares: the four corners and center.

Use the following formula for the hemocytometer: number of sperm in million/ml = number of sperm in 5 squares x 5 x 10,000

For a counting chamber, use the factor provided (instead of 10,000) which is derived from the volume of the chamber.

This gives an approximate count. For a more accurate count, dilute 10 µl of sperm suspension into 90 µl of diluting fluid (distilled water), count as above and multiply by the dilution factor of 10.

An alternative method of counting can be used with a hemocytometer. Determine the number of spermatozoa in one of the smallest squares

(1/16 of a large square). See the following table to determine the sperm concentration using a hemocytometer.

Determine the sperm concentration using a hemocytometer

Number of sperm per 1/6 square!	Bnmbdmsq'shnm 6"x10/ml
1	7!
2!	01!
3!	05!
4!	1/!
5!	13!
6!	17!
7!	21!

Note: Sperm concentration should be read twice. Determine the final number by averaging the two measurements.

After determining the sperm concentration in the sperm suspension, record the result on the TRAVAIL - H Results Form.

Severe Male factor:
Sometimes only one sperm parameter is abnormal and sometimes several are abnormal. An indicator useful in determining overall fertility is called the total motile count. This number

represents the total number of motile sperm in the ejaculate. The total motile count is calculated thus:

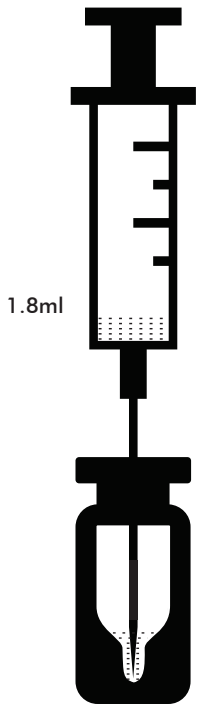
Ejaculate volume X Sperm Concentration X %Motility = TMC If the TMC is 20 million sperm or less, there is likely to have a male factor problem. Men with a TMC consistently less than 5 million are said to have 'severe' male factor infertility. It is not recommended to treat Infertile couples with severe male factor using TRAVAIL – H.

6. SPERM PREPARATION TECHNIQUES OF TRAVAIL – H

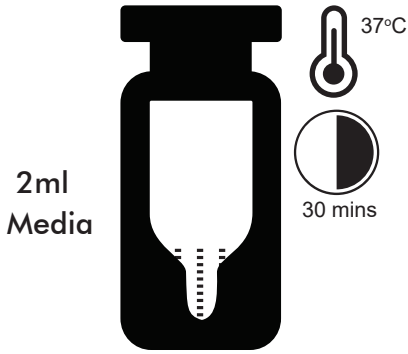
Following semen analysis, the sample is prepared using the following techniques:

Note: If a technical problem arises during the treatment of the sample, the supernatants can be reprocessed and used for insemination or to increase the final count of motile sperm.

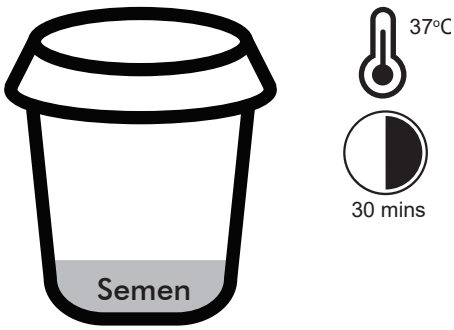
STEP 1:
Add 1.8 ml of w.f.i to TRAVAIL – H device.



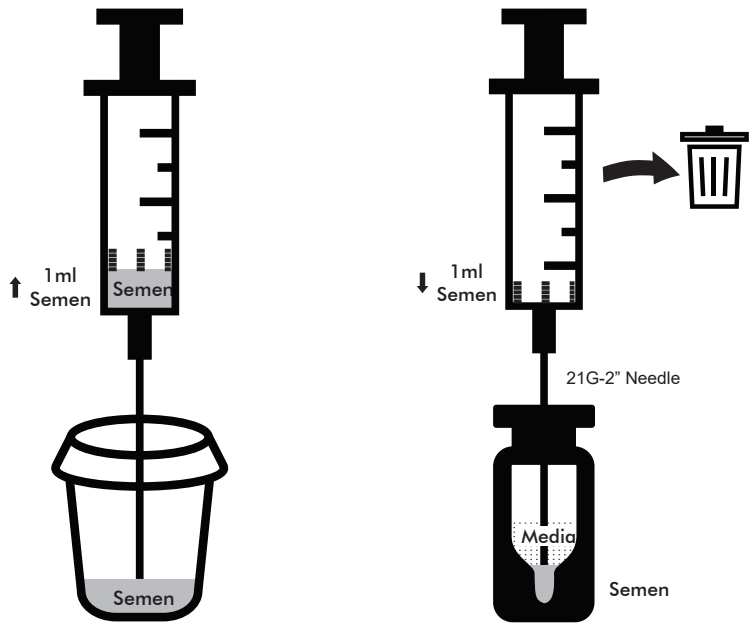
STEP 2:
Shake well and keep it in the heating block at 37°C for not less than 30 mins.



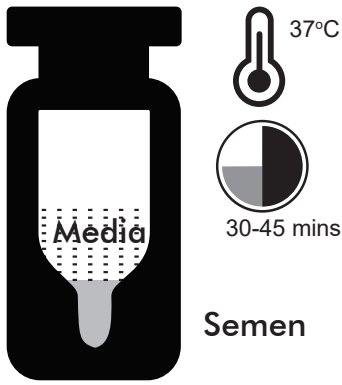
STEP 3:
Keep the semen container at 37°C surface for minimum of 30 mins to allow the semen to liquify and becomes homogenous mixture.
Note: If the semen sample is too viscous, add 0.5ml - 1ml of saline



STEP 4:
Use 21-G, 1.5 inch needle aspirate about 1 ml of semen sample and load into the device piercing through septa. Remove syringe along with the needle and discard.

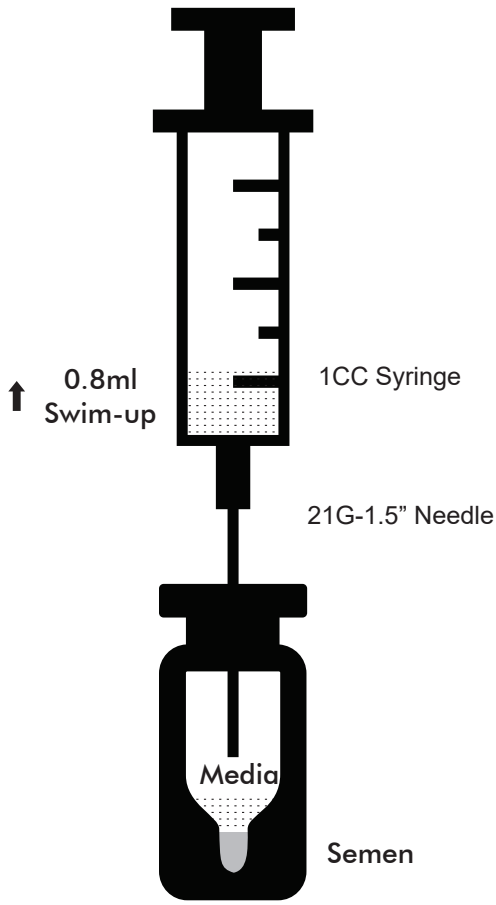


STEP 5:
Keep the device undisturbed in the heating block for 30-45 mins for sperm swim-up. During this step active motile sperms swim to the top leaving the less motile and immotile (dead) at the bottom of the device.

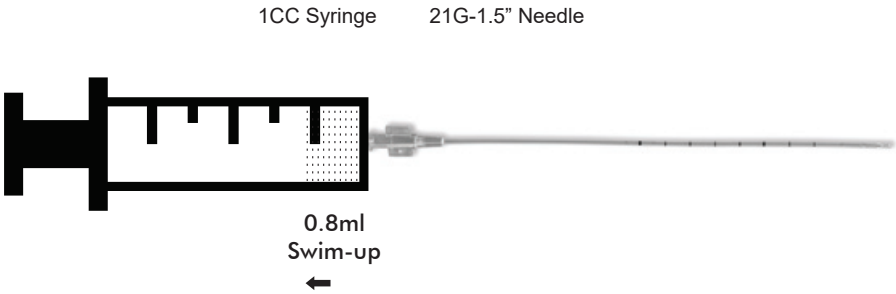


STEP 6:
After the incubation period, use 21-G, 1 inch needle to separate the swim-up fraction from the Device. Aspirate not more than 0.8ml.

Note: Do not shake the device while performing this step as it could lead to mixing of semen and media layers.



STEP 7:
Engage the IUI catheter to the syringe containing swim-up fraction and perform the insemination.



For the instructions on how to perform the insemination please refer to the 'INTRA UTERINE INSEMINATION' section below.

Note: If there is any difficulty in loading media/ sample into the Device, loosen the cap which allows smooth operations by allowing air to escape from the device.

XII) REFERENCES

1. Trounson A, Gardner DK. Handbook of In Vitro Fertilization. ISBN 0-8493-2922-1, Boca Raton Florida, p 46-50, CRC Press 1993.
2. Brinsden PR, Rainsbury PA. A textbook of In Vitro Fertilization and Assisted Reproduction. ISBN 1- 85070-323-X, p 172-8, Parthenon publishing 1992.
3. Edwards R, Brody S. Principles and practice of Assisted Human Reproduction. ISBN 0-7216-3626- 8, p 88-93, Saunders, Philadedelphia1995.
4. 5 Isolate manufacturer instructions, IRVINE SCIENTIFIC, 2511 Daimler Street, Santa Ana, CA 92705.

7. INTRA UTERILE INSEMINATION

I) MATERIALS AND INSTRUMENTATION

Disposable Equipment

a. Sterile syringes, 10 ml (2) and plastic cup, 100 ml (1) (for flushing the cervical area)
1. Sterile gauzes 4 x 4 (10)
2. Cotton balls or gauze 2 x 2(1 pack)
3. IUI Catheter (1)
4. Powder-free gloves (1)

Non-disposable Instrument

1. Heating Block
2. Speculum (1)
3. Ring forceps (1)
4. Pozzi tenaculum (1) used to pull on the cervix in case of a difficult transfer (try to avoid using it)

IV) QUALITY CONTROL

1. Check temperatures of the refrigerator and incubator daily using NIST thermometers. Record temperatures on specials forms posted on or near the instruments.
2. Verify that the sterilization indicator, located on the packaging of the autoclaved instruments, has changed indicating a proper sterilization process.
3. Verify that the package containing the IUI catheter is intact before opening and that the expiration date is valid.
4. Recalibrate the vaginal transducer every 6 months according to the manufacturer's specifications.

5. Review forms with the Travail - H results (daily by the Medical Director and monthly by the staff during the quality control meeting).

V) PROCEDURE

Warning: Protective barriers (e.g. gloves, glasses) are recommended when working with exposed biologic materials.

STEP 1:
PATIENT ADMISSION

Verify the identity of the patient

STEP 2:
PREPARATION OF THE VAGINA

Preparation of the vaginal cavity is generally performed before IUI

Note: Wear sterile, powder-free gloves during the retrieval. Change gloves after preparation of the vagina.

1. Place patient in a dorso lithotomy position and place speculum in the vagina
2. Swab vagina with cotton balls soaked in saline to wipe off mucus and vaginal dis charge. The vaginal cavity can be washed thoroughly using 10 ml syringes and saline (placed in 100 ml plastic cup)
3. Physician washes hands thoroughly and changes gloves.

STEP 3: INSEMINATION

1. Place the tip of the catheter at the external ostium of the cervix
2. Introduce the catheter with a gentle motion

inside the cervix. Try to avoid any inner cervical bleeding.
3. Advance the catheter slowly until the end of the catheter is located 1 to 1.5 cm from the top of the uterus either based on ultrasound guidance or based on a previous hysterometry.
4. Expel the PREPARED SPERMS into the cavity by pushing on the piston of the syringe.
5. Disengage the syringe keeping the catheter in the cervix and aspirate 0.8 ml of air into the syringe. Reengage and perform STEP 4 for completely emptying the catheter.

Note: Very important, patient may feel uterine contractions due to a difficult cervical passage of the IUI catheter or due to the positioning of a tenaculum on the posterior lip of the cervix. Wait that she feels no uterine contractions before expelling the prepared spermatozoa in the uterine cavity.

1. Withdraw the catheter slowly by keeping pressure on the piston of the syringe to avoid re-aspirating the syringe

Note: very important. Never release the pressure on the syringe until the tip of the catheter is out of the cervix.

STEP 8:
LUTEAL PHASE SUPPORT AND PREGNANCY ASSESSEMENT

The luteal phase (second half of the menstrual cycle following ovulation) is generally supplemented with progesterone or hCG (drugs that help embryo implantation). The type of drug, dose, and way of administration, will depend on the routine protocol used by the Reproductive center.

A pregnancy test will be performed 14 days after the IUI and if positive, will be repeated 2 days later. If a pregnancy has been detected it will be confirmed by the presence of fetal heartbeat (detected by ultrasound) at 5 weeks after IUI. The pregnancy will be then followed in the same way as a regular pregnancy. The outcome of the birth will be followed by the infertility specialist.

VI) REPORTING RESULTS

Report results of the IUI on the Travail - H Results Form

8.REPORTING RESULTS REPORTING RESULTS

I) REPORTING RESULTS OF AN TRAVAIL - H PROCEDURE Record all the steps of Travail - H including sperm preparation, and insemination on the Travail – H Results Form (appended). There should be a unique identification number for the patient as well as the name of the physician treating the patient. The physician or his laboratory assistant who performs the procedure should initial the T Results Form, and then it should be reviewed and signed by the Medical

Director in charge with particular emphasis on quality controls.

II) RECORD FORMAT

Records of the Travail – H procedures should be retained as either original paper records, or be saved electronically, or as photocopies, or on microfiche or microfilm. If retained as original paper record, the records should be indelible and legible. There should be a backup system of recording.

Manually transcribed results transferred electronically should be verified by the Medical Director to eliminate any potential data entry errors. If the Travail - H procedure results are entered electronically, they should be reviewed by the Medical Director and signed electronically or on a printed copy which is maintained as the original record. In either case, quality controls should be in place to assure both the validity of the results and recoverability of the records.

III) DATA RETENTION

Results and quality controls should be retained in a manner that allows for prompt retrieval of information. They should be reviewed again and analyzed at regularly scheduled quality control meetings (usually monthly or biweekly with all the pertinent Travail – H Center staff). Attention should especially be paid when results fall within critical ranges (i.e. very low sperm concentration or motility, ovulation...etc) and in the cases of patients who have not become pregnant by Travail - H, changes in the procedure should be considered and implemented for the next Tra-

vail - H cycle.

If incorrect (erroneous) patient results are identified, the revised patient report should be reported with the previous incorrect results. Both original and revised patient results should be signed by all individuals who have modified and revised patient data, control files, or computer programs. They should be retained for at least 2 years.

INFORMED CONSENT FORM

Woman's Name:.....

Man's Name:.....

Address/Telephone: .....
.....

It is important that you read the following document very carefully before you sign it. The signature of both members of the couple at the bottom of the document is essential. This signature means that you received answers to all your questions as well as all the clarification that you expected concerning the study.

PROCEDURE

The T procedure is an alternative IUI procedure where preparation of gametes (sperm) take place in a laboratory environment (i.e. in centrifuge), the fertilization occurs in fallopian tubes of women. In the Travail - H procedure the device replaces the laboratory equipment and provides superior environment for protecting sperm functions. Patients will be treated with standard drugs used in fertility treatment to allow production of several eggs. Monitoring will be performed by standard methods.

The woman will be monitored to determine if she becomes pregnant. This process will require approximately 3-5 visits to the center, not including visits for unforeseen needed care. The Travail - H device is made of two parts. The micro- chamber is situated at the bottom of device; this part contains the media coating. The upper

part is swim- up chamber where segregation of motile sperms happens in the procedure.

Ovarian stimulation

Follicles are ovarian structures in which the oocytes (eggs) are found. Stimulation of the ovaries with “fertility drugs” allows the production of several follicles on each ovary. The follicle growth is monitored by blood tests and ultrasounds and adjustments in the dose of drugs may be made based upon your response to the drugs. It is important that you accurately follow the prescribed drug treatment. If you have a doubt about the dose or way to inject the drugs don’t hesitate to call your Investigator/Physician or his/her assistant. The drugs and the injection protocol are identical to the ones used in IVF.

Ovulation induction

When the follicles have reached their maximum growth, you will be instructed to inject a drug (hCG) to cause the eggs to mature. This injection is to be performed at a precise time, generally in the evening. You must inform your physician immediately if for any reason the injection could not be done at the prescribed time. A change in the time of hCG injection may require a change in IUI and sometimes may require cancellation of the treatment cycle.

Sperm collection and IUI

The couple will report to the physician’s office prior to the scheduled time of the IUI The male partner will provide a sperm sample at the clinic before the egg retrieval. After washing and rinsing carefully hands and genital area with soap

and water, sperm collection is done by masturbation in a sterile container provided by the clinic. After collection the sperm is prepared in the travail - H device, after analysis (low sperm concentration and/or motility) a second sample will be requested. If the quality is still poor the Travail - H cycle will be canceled.

Intra Uterine Insemination

After 30-45 mins the prepared sperm will be transferred into the uterus using a catheter (thin tube introduced through the orifice of the uterus)

Luteal phase support and pregnancy assessment

The luteal phase (second half of the menstrual cycle following ovulation) is generally supplemented with progesterone or hCG (drugs that help embryo implantation). The type of drug, dose, and way of administration, will be prescribed by your Investigator / Physician and depends on the routine protocol used by the IVF clinic.

A pregnancy test will be performed 14 days after the IUI and if positive, will be repeated 2 days later. If a pregnancy has been detected it will be confirmed by the presence of fetal heartbeat (detected by ultrasound) at 5 weeks after the IUI. The pregnancy will be then followed in the same way as a regular pregnancy. The outcome of the birth will be requested by the infertility specialist investigator of the study.

Risks

Your participation in this procedure will subject you to the same risks as in a standard IVF cycle (see section1below). However a few additional potential risks related to the Travail - H procedure could occur. They are described in section 2 below.

a) Risks that could occur in both TRAVAIL - H & IVF procedure. Anxiety, depression of varying degrees, weight gain, fatigue, headache and sleep disorders are common side effects during infertility treatment. Specialized counselors and social workers are available. Irritation, redness and swelling may result from the injection of fertility and other drugs. Hematoma and/or infection may result from frequent blood drawing performed during the monitoring of the ovarian stimulation. Medications may cause allergic reactions or anaphylactic shock.

The long-term effects of the administration of fertility drugs are not known. The repeated use of infertility drugs had been suspected to increase the risk of gynecologic cancers; to this day this potential risk has not been demonstrated.

Fertility drugs used in IVF and TRAVAIL - H treatments are associated with an increase risk of ovarian hyper stimulation and multiple births

High order multiple births; including triplets, quadruplets, and quintuplets, have occurred during infertility treatments at a rate of approximately 5 % of all pregnancies. To prevent most

of the high order multiple births, the higher number of embryos to transfer has been limited to two. A multiple pregnancy causes risk for the mother and for the babies.

Contamination of the culture medium and gametes, may occur (expected in less than 2 % of cases) resulting in termination of the procedure. It is possible that fertilization may not occur. Embryo development may be arrested or abnormal.

Travail cycles require a substantial amount of time, effort and sacrifice from the participants which may result in more anxiety and disappointment if pregnancy does not occur. If pregnancy occurs,the usual risks of an ectopic pregnancy or miscarriage are still present. If delivery occurs the child or children may be stillborn, have chromosomal abnormalities and/or congenital birth defects.

Unforeseen complications or incidents can arise during the course of any treatment protocol. The quality of our standard medical care should keep the incidence of all these risks to a minimum. In emergency contact Dr..... at telephone number: ..... or

PATIENTS STATEMENT

We have read and understood the previous pages of the consent form and the Physician has explained the details including the possible risks and benefits of this treatment study. We obtained answers to all our questions and we

understand that we are free to ask additional questions. We understand that this is an investigations study and that unforeseen side effects may occur.

We consent to participate in this study and have been given a copy of this form.

Woman's name: _____

Date of birth: _____

Man's name: _____

Date of birth: _____

Woman patient (signature) Date

Man patient (signature) Date

TRAVAIL - H RESULTS FORM

Female Patient Name: _____

_____

D.O.B: _____ Age: _____

Male Patient Name: _____

_____

D.O.B: _____ Age: _____

ID Code: _____

Consent Form Signed: Y / N

Diagnosis: Infertility I / II 1st Preg.

Date:_____

Del / Misc / Ecto. 2st Pregnancy date:

_____ Del/Misc / Ecto

Cause: Unexplained / Male / Endo / Ovulation /

Other: _____

OvarianI nduction: Natural / MildStim / CC /

FSH / hMG / Antagonist / Other: _____

_____

hCG5,000 IU / hCG10,000 IU

Date: _____ Time: _____

Ovulation:

Date: _____ Time: _____

Number of follicles : _____ Ruptured: _____

Tech Initials: _____

Insemination: Date : _____ Sperm

concentration: _____/ml

Luteal Phase Support: Y / N Type: _____

Dose: _____ Pregnancy / Ongoing /

Miscarriage / Ectopic / Birth

Travail - H : _____ ____

Saline Solution Lot #:

_____ Comments:

Reviewed By: _____

Signature: _____

Maintenance of Sperm Collection Room

The sperm collection room is frequently one of the first physical locations and contact that the male patient has with the infertility practice. This first impression will reflect the type of professional expertise and quality of care that the patient may expect from the Clinic. It is essential that the collection room appears as comfortable, cleaned, and neat as possible. The person responsible for sperm collection is responsible for maintaining the cleanliness of the sperm collection room.

1. BEFORE SPERM COLLECTION

1. Before the first patient uses the bath room/ collection room, check that it has been correctly cleaned by the cleaning staff the evening before or by the last person using it.
2. Check the sink and toilet are clean and dry.
3. Check the trash basket has been emptied of all paper and used towels from the previous day.
4. Check the hamper containing soiled towels has been emptied.
5. Verify the floor and any furniture in the room is clean.
6. Check that the magazines or videos are nealy organized.
7. Place a sterile sperm collection container still wrapped and a clean towel in the room for the patient to use during collection.
8. Verify that a marker is available for the patient to mark the sperm collection container.

2. AFTER SPERM COLLECTION

The collection room must be prepared for the next patient. This includes the following actions:

1. Rinse out the sink with water and soap.
2. Flush the toilet.
3. Clean any spills observed with paper towels and 70 % alcohol solution available in the collection room.
4. Put the soiled towel in the hamper if it was not done by the patient.
5. Discard soiled paper towel or any paper in the trash.
6. Reorganize the magazines in the wall holder if needed.
7. Refresh the air using the can of air freshener available in the room.
8. Prepare if necessary a new towel and container for the next collection.

3. END OF THE DAY

Clean the room after the last sperm collection as previously described.

Check to make sure that there are enough containers and towels stored in the closet and available for the next day's appointments.

PATIENT INSTRUCTIONS

Instructions for Providing a Semen Sample

1.) Semen collection in the physician's office

A.) Avoid any medications before or during the test. If you are currently on medication, give the name of the medication to your physician before you start an T cycle.

B.) Avoid extremely hot baths, hot showers, saunas, or whirlpools for at least two weeks before the test, as exposure of the scrotum to high temperatures may affect sperm motility.

C.) Period of abstinence. The sperm preparation for insemination in IVF requires that you abstain from ejaculation for two to five days prior to the test.

D.) Collection container. A sterile, wrapped plastic container for collection will be provided by your physician or a staff member when you arrive.

E.) Empty your bladder prior to collection

F.) Thoroughly wash your hands, penis, and genital area with soap and rinse carefully with warm water. Avoid any soap residue, as soap is very toxic to spermatozoa.

Note: It is very important that the previous instructions be carefully observed so that the results of any following reproductive procedures will not be affected.

G.) Collect semen by masturbation in the collection room. Open the plastic wrapper, discard it in the waste container, and remove the cap from the specimen cup. Collect the ejaculate in the sterile container.

Note: Drops of liquid may be observed in the container provided to you; they are drops of culture medium or saline solution used to rinse the container and eliminate plastic residues.

If there is a loss of part of the ejaculate during the collection, please inform your physician or his/her assistant.

H.) Do not use any lubricants of any kind including saliva. Be careful not to touch the inside of the cup or cap.

After collection, replace the cap on the specimen cup. Using the available marker, label the container with your last name, first name, date of birth, and the date and time of collection. Put the container in the plastic bag (which can be found near the container) and holding the bag vertically, bring it to the physician.

Note: Sperm collection by intercourse is not recommended because of the risk of loss of the first portion of the ejaculate, which usually contains the highest concentration of spermatozoa. A second reason is the high risk of contamination by vaginal secretion. The method of sperm collection should be recorded if not performed by masturbation.

2.) Semen Collection at Home

A.) Container for collection. For the collection, it is recommended that you use the specimen container and the plastic bag available from our facility to transport the specimen.

B.) Delivery Expectations. The specimen should be delivered to the laboratory within one hour of collection. Keep the sample between 70°F and 80°F; transport the container vertically in the plastic bag (for instance, by putting in a jacket pocket).

C.) If Collection by condom is required, you may purchase a non-toxic condom from our office. After collection, tie the condom to avoid loss of semen and put it in a sterile container and place the container in the plastic bag during transport to the physician office.

D.) The container should be labeled with your last name, first name, date of birth, and the date and time of collection. Please use a marker when writing this information of the container.

E.) After collection, the sample must be brought to the office located:

Address: _____

_____

Telephone: _____

Travail™

Intra Uterine Insemination Kit

TREAT EARLY

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MEDICAL
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