ASSESSMENT OF THE EFFECTIVENESS AND EASE OF USE OF DIRECTVISION- A DIRECT VISION SYSTEM FOR URINARY CATHETERIZATION: RESULTS OF A SINGLE-CENTRE PROSPECTIVE STUDY

INFORMED CONSENT FORM

Good medical care includes obtaining informed consent before beginning any experimental procedure or research. "Informed consent" is a process. We will tell you about the nature, purpose, alternatives and possible side effects of the research, and then you decide whether or not you want to take part. This research study is being conducted by Dr Mohamed Etafy.

Principal Investigator(s): Mohamed Etafy, MD

Sub-Investigator(s): Sijo Parekattil, MD
Jamin Brahmbhatt, MD

Sponsor: PercuVision LLC

Investigational Site(s): South Lake Hospital

We are asking you to take part in a research study. This consent form gives detailed information about the research study. Your doctor will discuss this information with you. Please ask any questions you may have. If you agree to take part in the research study, we will ask you to sign this form. You can change your mind and withdraw your consent at any time. There is no penalty to you if you do this.

1. PURPOSE OF RESEARCH STUDY:

We are asking you to be part of this research study because you currently require a urinary catheter to drain your bladder and the nursing staff has tried placing one for you however was unsuccessful. Therefore the nursing staff has called us, the Urology team to come and place the catheter for you. Usually once a patient had one failed catheter placement, we place a catheter via cystoscopy which is the standard of care. A cystoscopy is an endoscopy of the urinary bladder via the urethra. We now have a new technology called DirectVision which is a camera within a urinary catheter essentially combining the functionality of a urinary catheter with a cystoscope. The purpose of the research study is to discover which techniques (cystoscope or DirectVision) is more effective, less troublesome and cause less pain, infection or bleeding in the urine.

2. EXPECTED DURATION:

If you decide to take part, you will receive treatment on this study for difficult urinary catheterization. After that, we will continue to check on your health for 1-3 days during your admission.

3. PROCEDURES TO BE FOLLOWED:

If you are agree to be in this study, we will assign you to either be in Group A (catheter placement via cystoscopy) or Group B (catheter placement via DirectVision). We do not know if any group will be better for you. Currently, catheter placement via cystoscopy is the standard of care.

- Participants in *Arm / Group A* will have catheter placement using the cystoscopy method.

After you sign your consent, your genitalia will be cleaned. A numbing jelly will be applied to your urethra to help prevent pain when the instrument is inserted. After waiting a few minutes for the numbing, the urologist will carefully push a hollow tube equipped with a lens (cystoscope) into your urethra and slowly advanced it into your bladder. A sterile solution will flow through to flood your bladder. This makes it easier for your doctor to see what's going on. The fluid might give you an uncomfortable feeling of needing to urinate. Once inside the bladder, a wire will be left in and the cystoscope will be removed then a catheter will be placed using the wire and you are done. With local anesthetic, your cystoscopy may take less than 20-30 minutes.

- Participants in *Arm / Group B* will have catheter placement using DirectVision.

After you sign your consent, your genitalia will be cleaned. A numbing jelly will be applied to your urethra to help prevent pain when the instrument is inserted. After waiting a few minutes for the numbing, the urologist will carefully push the DirectVision device; a curved tip catheter with a camera embedded in it into your urethra and slowly advanced it into your bladder. A sterile solution will flow through to flood your bladder. This makes it easier for your doctor to see what's going on. The fluid might give you an uncomfortable feeling of needing to urinate. Once inside the bladder, the balloon of the catheter will be insufflated and you are done. With local anesthetic, your cystoscopy may take less than 15-20 minutes.

All the procedures done via flexible cystoscopy or DirectVision will be billed to your insurance.

4. IDENTIFICATION OF EXPERIMENTAL PROCEDURES/TREATMENTS:

DirectVision is an innovative device from the PercuVision Company which is FDA-registered and approved for use in difficult urinary catheterization setting.

5. POTENTIAL RISKS AND DISCOMFORTS:

The treatment used in this program may cause some of the side effects such as bleeding, burning sensation with the catheter, infection. In addition, there is always the risk of very uncommon or unknown side effects occurring. The doctor may prescribe medication to keep the side effects under control.

6. POTENTIAL BENEFIT TO YOU OR OTHERS:

Your taking part in this research study may help others in the future who have similar conditions.

7. ALTERNATIVE PROCEDURES OR TREATMENTS:

If you decline to participate in this study, your urinary catheter will be placed using the standard of care practice which is via cystoscopy.

8a. CONFIDENTIALITY OF RECORDS:

Your signed consent will be kept in a confidential form in a locked office of the investigators and maintained for a minimum of three years after the completion of the study.
The confidentiality of your record is carefully guarded. The data collected from your procedure will be stored in electronic files on protected computers.

Publications from this study will not contain any information that can identify you, No information that can identify you will be released to any third party except as provided herein or as required by law.

8b. AUTHORIZATION TO USE OR DISCLOSE PROTECTED HEALTH INFORMATION (PHI) FOR RESEARCH:

The Federal Privacy Regulations explain how your personal health information will be used and to whom it will be disclosed (given to) for this research study. You will get a copy of the Notice of Privacy Practices, which describes the Orlando Health, Inc. privacy practices. Your protected health information may be used or disclosed for research purposes.

We will gather details such as your name, address, age, sex, urological history, indication for Foley catheter placement, number of attempts by referring service, level of training of the person who tried placing the catheter, time to place catheter via DirectVision/cystoscope, instruments used, findings of the procedure, adverse outcome, degree of difficulty, presence of pain and hematuria.

Who may Use or Disclose your Protected Health Information?
The following individuals / organizations may use or disclose your protected health information for this research study:

- Study doctor and the study staff
- Orlando Health Institutional Review Boards
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To whom may your Protected Health Information be Disclosed?
As part of the study, the study doctor and the study staff may disclose the results of study-related tests and procedures that may identify you to the following:

- PercuVision
- Orlando Health Institutional Review Boards
- Food and Drug Administration (FDA) (if applicable)
- Office for Human Research Protection (OHRP) (if applicable)

In addition to the list of individuals and organizations to which your Protected Health Information may be disclosed, others, who are not currently known, may receive the information. If information from your records is given to any of these people, they might give it to someone else. If this happens, the information will no longer be protected. Orlando Health, Inc. expects anyone who receives the information to protect it. However, Orlando Health, Inc. cannot always keep that person from giving it to someone else. Your PHI may no longer be protected by the Federal Privacy Rule once it is disclosed by the study doctor to these other parties.

By agreeing to participate in this research study and signing this informed consent, you are authorizing Orlando Health, Inc., South Lake Hospital, and Dr Mohamed Etafy to use and disclose your protected health information for the purpose of research related to this study. Only the smallest amount of protected health information necessary will be used. At the time that your records no longer need to be checked, the PercuVision, and Orlando Health, Inc. will destroy (shred) your research records.

Additional information about confidentiality of and access to your protected health information while you take part in this research study:

- If your doctor wishes to use your identifiable information for any other reason than this research study, he/she must get your permission for that purpose.
- You may withdraw your permission to use your protected health information by talking with your doctor or research staff and making a request in writing. Use and release of information that was already gathered may continue when necessary in checking and reporting important events [such as accounting for your withdrawal from the study, and any adverse events reported to the FDA to monitor safety of participants, or federal regulatory agency audits (reviews)].
- If you withdraw your permission to use your health information, neither Orlando Health, Inc. nor Dr Mohamed Etafy will release information collected after your withdrawal to PercuVision or any other third party.
- If you withdraw your permission to use and release your health information, you will no longer be able to take part in the study. However, if you decide to withdraw from the study, you will not be penalized or lose benefits to which you are otherwise entitled.
- Your doctor may discuss other research projects with you if he/she thinks the other projects relate to your condition. However, your health information cannot be given to another doctor or sponsor for the reason of asking you to enroll in another research study unless you give your permission for this.

9. COMPENSATION:

There will be no compensation to you during this study.

10. RESEARCH RELATED INJURY:

In the event that injury occurs as a result of this research, treatment will be available. However, you will not be reimbursed by Orlando Health, Inc. or the investigator for these costs. You do not waive any of your legal rights by signing this form.

11. QUESTIONS

For more information about your rights as a research participant, you may call the Institutional Review Board Office, at (321) 841-5895.

The study doctor involved in your care is available to answer any questions you have concerning participation in this research program. You are free to call Dr Mohamed Etafyat 352-536-8761 with any questions concerning this research study that you have now or in the future.

12. VOLUNTARY PARTICIPATION:

You are free to refuse or stop participation in this research study at any time without penalty or loss of benefits to which you are otherwise entitled. You are free to seek care from a physician of your choice at any time. If you do not take part in or withdraw from the study, you may continue to receive care for which you will be financially responsible.
If you decline to participate in this study, your urinary catheter will be placed using the standard of care practice which is via cystoscopy.

13. ADDITIONAL RISKS:

Participation in this study may involve risks to you which are currently unforeseeable.

14. INVOLUNTARY TERMINATION:

Your participation in this study may be stopped by the study doctor or sponsor under the following circumstances:
Inability to tolerate placement of urinary catheter via cystoscopy or DirectVision under local anesthesia therefore requiring the procedure to be done under general anesthesia.

15. PROCEDURES FOR WITHDRAWAL:
When you complete the study or should you for any reason stop participating in the study, you will be followed for 1-3 days during your admission to ensure adequate Foley catheter drainage.

16. NEW FINDINGS:

We will let you know about any significant new findings found during the procedure right away

17. NUMBER OF PARTICIPANTS:

We expect to enroll about 75-100 at this site. The total number enrolled at all sites will be 75-100 participants.

18. ADDITIONAL COST:

All the procedures done via flexible cystoscopy or DirectVision will be billed to your insurance.
Participation in this study will not result in any additional costs or medical bills that are your responsibility.

19. FINANCIAL DISCLOSURE:

This clinical research study is paid for by the sponsor, which makes one or more of the drugs/devices being tested. Research monies may help support the research and educational programs of the hospital.

20. ADDITIONAL INFORMATION:

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

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21. **SIGNATURES:** My signature indicates that I consent and authorize Dr Mohamed Etafy and whomever he (she) may designate as his (her) assistant(s) including Orlando Health, Inc., its employees and its agents to perform the research described above.

I AM MAKING A DECISION WHETHER OR NOT TO PARTICIPATE IN THIS STUDY. I HAVE READ, OR HAD READ TO ME IN A LANGUAGE THAT I UNDERSTAND, ALL OF THE ABOVE, ASKED QUESTIONS, RECEIVED ANSWERS CONCERNING AREAS I DID NOT UNDERSTAND, AND WILLINGLY GIVE MY CONSENT TO PARTICIPATE IN THIS STUDY. UPON SIGNING THIS CONSENT FORM, I WILL BE GIVEN A SIGNED AND DATED COPY.

_____
PRINTED NAME OF RESEARCH PARTICIPANT

_____ _____
Signature of Participant or Legal Representative Date

_____ _____
Signature of Witness (when required) Date

I have explained and defined in detail the research procedure(s) in which the research participant has consented to participate.

_____ _____
Signature of Investigator/Designee Obtaining Consent Date

Interpreter

Name_____ Phone#_____

Address_____

For Signatures by a Legal Representative, please describe the authority to act on behalf of the participant below: