


YOUR GUIDEBOOK TO THE



OASIS STUDY



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Welcome to OASIS

WHAT IS AN OASIS?

In the midst of a desert, an oasis is a place with water and plants, where a caravan would stop to rest, and animals would come to drink and find shade. Desert travelers have always welcomed the sight of an oasis on the horizon. It can also mean a relaxing stopping point – a quiet room, a green park, or a peaceful place to visit in your mind. It is something that provides refuge, relief, or pleasant contrast.

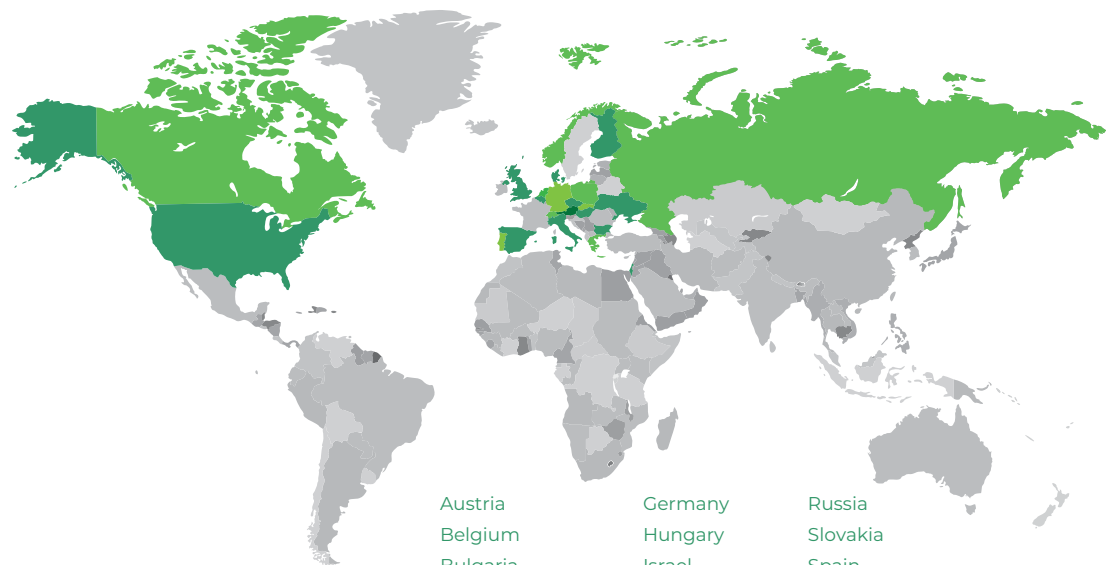
Oases are found in desert or arid regions around the world. One of the most picturesque oases called Crescent Moon Lake is located on the ancient Silk Road in Dunhuang, China.



OASIS Studies

The OASIS studies are part of a global program investigating the effectiveness and safety of a new investigational non-hormonal treatment for hot flashes associated with menopause, called elinzanetant. Bayer is conducting the OASIS studies to see if elinzanetant is safe and effective in reducing the number and severity of hot flashes and in improving the quality of life for postmenopausal women.

Women from over 23 countries, speaking more than 33 languages will participate in multiple OASIS studies. We expect that over 1340 women worldwide will take part.



| | | |
|----------------|-------------|----------------|
| Austria | Germany | Russia |
| Belgium | Hungary | Slovakia |
| Bulgaria | Israel | Spain |
| Canada | Italy | Switzerland |
| Greece | Netherlands | Ukraine |
| Czech Republic | Norway | United Kingdom |
| Denmark | Poland | United States |
| Finland | Portugal | |

What is a Clinical Study?

HOW IS A NEW MEDICATION DEVELOPED?

The development of an investigational new drug like elinzanetant runs through many phases. From an idea, until it is available in the pharmacy, might take more than 13 years. During most of this time, sponsors are conducting clinical trials to test how well a drug works and how well it is tolerated.

Condition



It all started with the decision to develop a new drug for patients suffering from hot flashes, for which no optimal drug is yet available.

Find how to attack the symptoms



Many years ago, researchers identified a target in the symptom aticevent: A molecule to which a drug could dock.

Inventing drug candidates



Pharmaceutical researchers invented the investigational drug substance elinzanetant that appeared to affect hot flashes.

Test for effect and tolerability



Pharmaceutical researchers tested elinzanetant in cell cultures and in studies with animals (unfortunately, this is still required) to make sure the substance is effective and non-toxic or otherwise harmful. All animal studies need to be approved by an Ethics Committee and the number of studies and animals is kept at a minimum.

After additional testing, elinzanetant became the active ingredient of the capsules you are now taking.

What is a Clinical Study

Phase I: Studies with a few healthy adults

Elinzanetant was then tested in several different dosages in trials with only a few women who were all healthy, i.e., were not suffering from hot flashes caused by menopause. By analyzing participant blood samples, researchers studied what the body did with the investigational drug, how long it stayed in the blood, and which dosage was more effective.



Development of the formulation

Next, the researchers had to find the most effective way for participants to take elinzanetant (i.e., as a tablet, capsule, ointment, drinking or injection solution, or a spray).



Phase II: Studies with women suffering from hot flashes

In this phase of the study drug development, clinical researchers tested the effectiveness, safety, and optimal dosage in trials in which approximately 300 women suffering from hot flashes participated.

It was confirmed that 120mg is the optimal dosage in study participants.



Phase III: Studies with many women

Currently, elinzanetant is being tested in several clinical trials in which participants from many countries are participating.

To prove elinzanetant is well-tolerated, safe, and effective; over a thousand women need to have been tested with elinzanetant over one year.



Assessment by the licensing authority

Once the data from all the women who participate are evaluated and if there is evidence that elinzanetant is well-tolerated, safe, and effective, Bayer will submit the entire dossier to the US Health Authority, FDA, and Health Authorities in other countries as well.

Only after their approval will elinzanetant be available in pharmacies so that other women suffering from hot flashes during menopause may benefit from the treatment!



We Hear You

BAYER: SCIENCE FOR A BETTER LIFE

Our mission statement, Science For A Better Life, motivates us throughout each step of creating new treatments and medications. At the center of everything we develop is you, the study participant. Understanding your daily journey and what it is like to have moderate to severe hot flashes has been at the core of the Bayer Study Team's focus as we prepare for the OASIS clinical studies.

At Bayer, we have been focused on ensuring that your perspectives and individual journeys are written into the study plan and considered throughout the study. We want to make sure that your experience before, during, and after participation is heard and that your voice is amplified.

The OASIS Study has been developed incorporating feedback from women just like you to support you in your experience as a participant in the OASIS Study.



We Hear You

To develop the OASIS Study with you in mind, we distributed surveys and conducted interviews with women just like you, who experience hot flashes associated with menopause, in countries across North America and Europe.

We learned from this that the impact of hot flashes is significant and causes daily disturbances in a woman's overall mood and sleep pattern. These symptoms frequently lead to women seeking out treatment; however, most doctors will offer hormonal therapy, even though many women prefer non-hormonal treatment. We know that a lack of options and access to educational materials on the efficacy of non-hormonal therapy is something that needs to be addressed.

HERE ARE A FEW OF THE STATEMENTS THAT WE HEARD FROM WOMEN IN OUR INTERVIEWS.

WOULD YOU PARTICIPATE IN A CLINICAL TRIAL?

Moderator: *If you look at the OASIS Study, what is the most attractive thing about it?*

Chantelle: *You learn a lot about menopause; you know that there's a solution on the way or that people are looking for a solution.*

HOT FLASH: WHAT HAVE YOUR DOCTORS DISCUSSED WITH YOU ABOUT YOUR OPTIONS?

Moderator: *Knowing what these treatments are, would you feel comfortable doing hormonal treatment if your doctor recommended hormonal treatment?*

Marina: *If the only symptom is hot flashes, no, I don't think so.*

Moderator: *Would you prefer to continue with a non-hormonal treatment?*

Marina: *Yes. For whatever reason, I just didn't want to. The effects might have been beneficial for hot flashes but could destabilize something else, hormonally speaking. When you change your hormones, I think it's something that could get out of control.*

We Hear You

HOT FLASH: WHAT DOES IT FEEL LIKE?

Moderator: *Can you describe hot flashes to me? Tell me how they feel for you and what your sensation is when you're having them.*

Cher: *Extremely uncomfortable almost everywhere in my body, at some times when it's really bad. It usually starts on the back of my neck. It starts to feel hot, as if I'm outside on a very humid Chicago day. Then, it goes to my face, and my face gets slightly flushed; then, the sweating happens so profusely that my entire back is covered in sweat and my arms; I'm literally wiping and wiping, and I have to sit in front of the air conditioner. It gets really bad.*

ENDOMETRIAL BIOPSY: DO YOU HAVE ANY QUESTIONS ABOUT THIS PROCEDURE?

Moderator: *What would you want to know about the endometrial biopsy? What would you ask your doctor?*

Donna: *What all does it entail? Is there pain? What are the risks? Am I sedated? Am I put to sleep? Is it just something that's done in the office, which it probably is? Those kinds of things.*

YOUR ONGOING FEEDBACK IS IMPORTANT

At Bayer, we will continue listening to you during your participation in the OASIS Study. You will have the opportunity to provide confidential feedback on your experience multiple times by taking a survey at the site or online. We appreciate your time and look forward to continuing to hear you.

YOUR OASIS STUDY INFORMATION

CHEBIKA, TUNISIA

This beautiful mountain oasis can be found at the foot of the Djebel mountain range, about 50km from the ancient city of Tozeur. A natural underground fountain is responsible for the Chebika Oasis.

The Informed Consent Process

WHAT IS INFORMED CONSENT?

Informed consent is a process of communication between you and your study doctor that will help you decide about your potential participation in the clinical study. Every participant has the right to receive information and ask questions before making a decision. During this process, you will receive an **Informed Consent Form** with information about the clinical study, investigational treatment, study tests and procedures, risks and benefits of participation, and your rights as a study participant.

Signing the Informed Consent Form means that:

- You have received all the information about the clinical study, and you had a chance to ask questions.
- You use this information to decide if you want to participate in the study.
- If you decide to participate, signing the Informed Consent Form means giving your consent (agreement). The completed and signed form is a legal document that allows your study doctor to enroll you in the study.

If new information becomes available during the study, which might affect your decision to continue your participation, it will be shared with you promptly. If you decide to continue, you will be asked to sign an updated Informed Consent Form.

You can change your mind at any time, even if you have already started the study treatment. Inform your study doctor if you want to stop participation in the study.

Study Visit Schedule

**YOUR PARTICIPATION
IN THE STUDY WILL LAST
UP TO 9 MONTHS**

| OASIS | | | | |
|---|----------------|---|---|--|
| 2-6 WEEKS | 12 WEEKS | 14 WEEKS | | 4 WEEKS AFTER STUDY TREATMENT PERIOD ENDS |
| SCREENING | BASELINE | STUDY TREATMENT PERIOD | | FOLLOW-UP |
| | | Elinzanetant or Placebo | Elinzanetant | |
| 1-3 VISITS* Determine whether you are eligible. *Screening Visits (1-3) can be combined, if time allows. | 1 VISIT | 3 VISITS You will have a 1 in 2 (50%) chance of receiving the investigational oral medication or placebo. Three On-Site Visits every 4 months | 3 VISITS You will receive the investigational oral medication. Two On-Site Visits and one Telephone Visit in between. | 1 VISIT Evaluate your overall health status after the investigational oral medication is stopped. |

Study Visits

SCREENING VISIT

During the Screening period, you will be evaluated to determine if you meet all the criteria to participate. Different procedures are required for this purpose; therefore, up to three visits may be needed depending on your study doctor's office set-up.

During Screening, the site staff will perform a physical examination, check your vital signs, ask about

your medical history and current medications, have blood draws and urine samples analyzed, and ask you to take a pregnancy test. In addition, we will perform an electrocardiogram (ECG), a transvaginal ultrasound, endometrial biopsy, cervical cytology, and a mammogram. You will find descriptions of these procedures in this booklet in the chapter *Procedures and Assessments*. Your study doctor will discuss any relevant findings with you.

We will also ask you to complete questionnaires and show you how to use an electronic diary (eDiary). You can view a training video and take a quiz on your device at any time. You will receive a Participant Quick Guide with instructions for the use of the eDiary. Your study doctor's team will answer all your questions to make sure you are comfortable using the device. A duly completed eDiary is a vital criterion to qualify for the study.



Study Visits

BASELINE VISIT

The status of your health and condition, at or before the Baseline Visit, will serve as a base for determining the effect of the study medication. During the analysis of study data, we will calculate changes in your condition compared to the baseline values.

At Baseline, we will again perform a physical examination, check vital signs, collect blood samples, review your current medications and ask you to complete questionnaires.



Based on your test results and completion of the eDiary, the study staff will determine if you are eligible to participate in the study. If you meet all the requirements, you will be assigned at random to receive either the investigational oral medication or placebo, a capsule that looks like the investigational oral medication but does not contain any medication. The study is blinded, which means neither you nor your study doctor will know which treatment you are receiving.

Study Visits

STUDY TREATMENT PERIOD

During the study treatment period, you will take the study drug every evening before you go to sleep. You will have five regular on-site Study Treatment Visits and one Telephone Visit so we can monitor your overall health status.

Starting from Study Treatment Visit 3, there will no longer be a possibility of getting the placebo. All study participants will receive the investigational oral medication, regardless of which option they were assigned to before. It is important that you bring all study medication you might have at home to this visit and return it.

At Study Treatment Visit 4, you will take the investigational oral medication at your study doctor's office. This means you need to skip the evening dose on the day before the visit. For all other days of the study treatment period, you will take the investigational oral medication at home.

During the entire study treatment period, it is very important that you regularly complete questionnaires, your daily hot flash diary, and study medication intake in the eDiary. Each entry is extremely valuable for the study!

When the study treatment period ends, you will come to your study doctor's office for the last Study Treatment Visit 6. Some of the tests and procedures that you have undergone during the study will be repeated. You will be instructed to stop taking study medication. All study medication still in your possession must be brought to this visit to be returned.

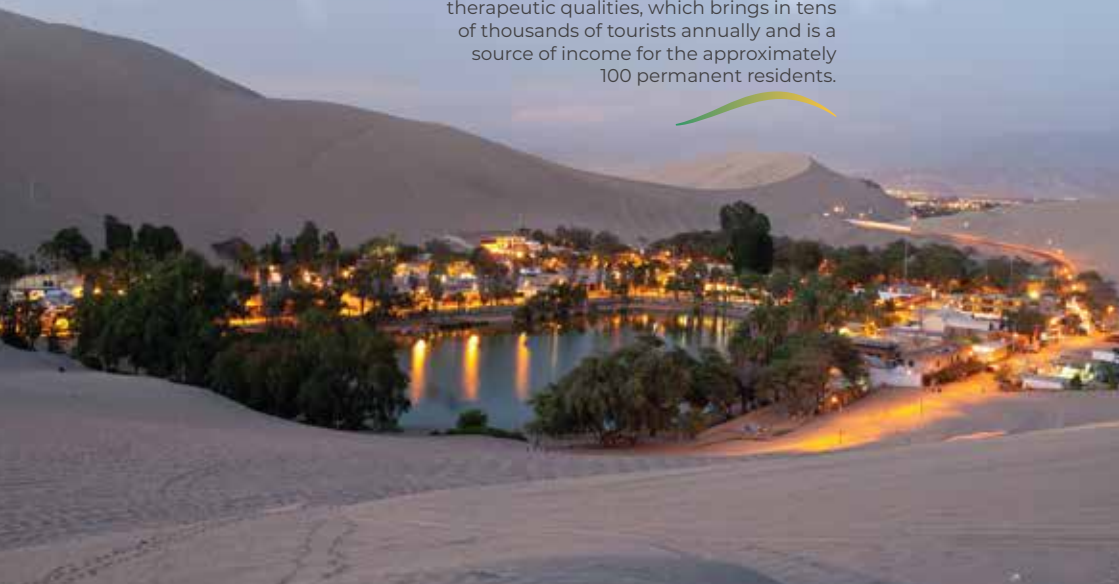
FOLLOW-UP VISIT

About four weeks after receiving the final dose of the study medication, you will come back to your study doctor's office for a Follow-up Visit. The Follow-up Visit is to check on your well-being and health before you complete the study.

YOUR STUDY MEDICATION

HUACACHINA, PERU

This village in Peru is built around a small oasis surrounded by sand dunes in southwest Peru. The waters and mud of Huacachina are thought to have therapeutic qualities, which brings in tens of thousands of tourists annually and is a source of income for the approximately 100 permanent residents.



Your Study Medication

The OASIS study is being conducted to learn more about an investigational oral medication called elinzanetant.

The study drug is packaged in a box with five blisters each containing 12 oblong capsules of either investigational oral medication or placebo.

Two capsules should be taken every evening before you go to bed. The capsules should not be broken, halved, or crushed. They should be swallowed whole with water.

If you forget your dose in the evening:

- until 2am the same night, take the dose immediately.
- after 2am skip the missed dose and take the next dose at the regularly scheduled time.

If you mistakenly take more than two capsules or incorrectly record your intake in the eDiary, please inform your study doctor.

It is very important that you take your study medication in the right dosage and at the right time every evening. Remember to record each time you take the study medication in the eDiary, reflecting the actual number of capsules you have taken. As a one-time exception, you will be asked to skip the evening dose prior to your scheduled Study Treatment Visit 4 and take the capsules on the following day, during your study visit at your study doctor's office. The amount of study drug in your blood will be measured at this study visit and on other occasions.

Make sure to bring all unused and empty study drug blisters to each study visit. Your study doctor's team needs to keep a detailed record of all capsules you have taken and how many are left.

Your Study Medication

REMINDERS ABOUT MEDICATIONS

There are certain types of medications you will not be able to take during the study. Your study doctor may have had you stop taking certain medications. Unless it is an emergency, it is important not to start any new medications without first telling your study doctor. Show your OASIS Study Emergency Contact Card to any doctor you are consulting to let them know you are participating in a clinical trial. If your doctor has any questions or needs to prescribe any new medication, have them contact your study doctor. Tell your study doctor right away about any changes to your medications, including:



New
prescription
medications



Changes to
medications—that is,
if you stop taking a
medication or begin
taking a different dose



New over-the-counter
medications or
supplements

Let your study doctor know as soon as possible about any changes in your health or if you are admitted to a hospital.

STUDY PROCEDURES AND ASSESSMENTS

WADI BANI KHALID, OMAN

In the country of Oman's shining seaside capital, there lies the Wadi Bani Khalid oasis nearly 200km away. Emerald pools of water and lush palms surround the rocky cliff faces in the middle of the desert of Oman.



Endometrial Biopsy

WHAT IS IT?

An endometrial biopsy is a medical procedure in which a small amount of tissue from the endometrium (the womb lining) is collected for examination under a microscope. The removed tissue is examined for cell abnormalities.

WHY IS IT DONE IN THE OASIS STUDY?

To adequately evaluate the safety of the study medication, your study doctor needs to be sure that there are no abnormalities in the lining of your uterus when you start the study. After completing the study, your study doctor will repeat the procedure to check for any potential cell abnormalities.

HOW IS IT DONE?

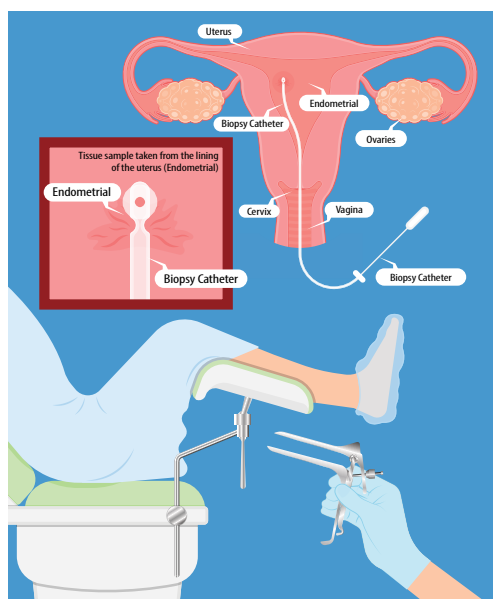
An endometrial biopsy is usually done in your study doctor's office. It is most often done without anesthesia. You will be placed with your feet in stirrups. Your study doctor will insert a speculum into the vagina to hold it open so that your cervix can be viewed (like a Pap test). Your cervix will then be cleaned with a special solution. Another instrument may hold the cervix steady while a very thin suction tube is inserted into the uterus to collect the tissue sample. The tissue will then be sent to a pathologist for analysis of the cells.

How long will it take?

The whole procedure will usually take between 5 and 15 minutes.

What are the risks?

An endometrial biopsy is generally a safe procedure. Like other intrauterine procedures, there is a small risk of infection. There is also a risk of puncturing the uterine wall; however, this is very rare. Some women might have light vaginal bleeding afterward.



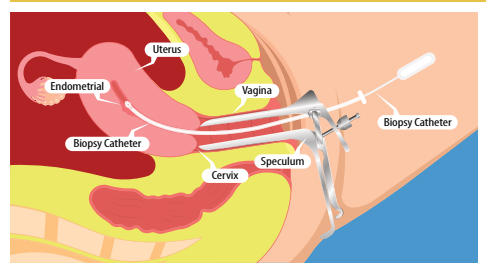
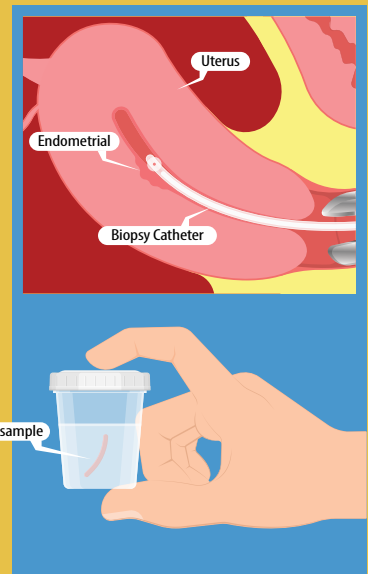
Endometrial Biopsy

WHAT TO EXPECT DURING/AFTER THE PROCEDURE?

You may experience pelvic pain and discomfort like menstrual cramps during the procedure. An analgesic (medication to relieve pain) can be used, if necessary. After the procedure, you may need to rest for a few minutes before going home. It is normal to have some mild cramping or vaginal spotting, or bleeding for a couple of days after the procedure. Take a pain reliever as advised by your healthcare provider.

You should contact your study doctor if you notice any of the following:

- Excessive bleeding, or bleeding longer than two days after the procedure
- Foul-smelling discharge from your vagina
- Fever or chills
- Severe lower belly pain



Transvaginal Ultrasound (TVU)

WHAT IS IT?

Ultrasound is the term used for high-frequency sound waves. Ultrasound examinations use these sound waves to produce an image onto a screen showing the inside of your body. Transvaginal ultrasound looks at the pelvic organs from inside the vagina using a special, smooth, thin, handheld device called a transducer. It is used to identify abnormalities in the uterus (womb), cervix (the neck of the womb), endometrium (lining of the womb), fallopian tubes, ovaries, bladder, or the pelvic cavity.

WHY IS IT DONE IN THE OASIS STUDY?

To adequately evaluate the safety of the study medication, your study doctor needs to be sure that there are no abnormalities in your womb and ovaries when you start the study.

HOW IS IT DONE?

After emptying your bladder, you will be asked to undress from the waist down and lie on an examination bed. A protective cover is placed over the transducer, and lubricating gel is applied to it. You will be asked to bend your legs, and the transducer is inserted into the vagina. It is gently moved around the inside of the pelvis, and images are taken. You might have your lower abdomen pushed with the examiner's hand to try and get some of the pelvic organs closer to the transducer for better pictures. The examination is carried out in "real-time," which means that the images you see on the screen show the inside of your pelvic area. Still photographs are also taken during the examination.

How long will it take?

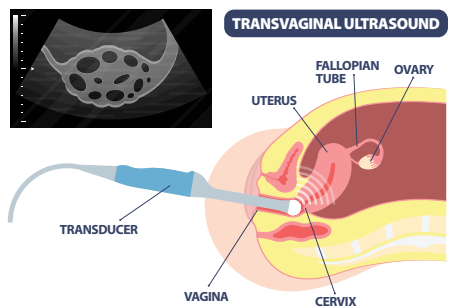
The examination takes between 15–30 minutes.

What are the risks?

There are no known risks of having a transvaginal ultrasound. It uses sound waves to obtain images, and there is no radiation involved.

What to expect during/after the procedure?

The exam may cause some discomfort but doesn't usually cause any pain and shouldn't take long. You may notice some slight vaginal discharge from the lubrication gel after the test, but this should stop within 24 hours.



Cervical Smear

WHAT IS IT?

A cervical smear test (or Pap test) consists of collecting a sample of cells from your cervix (the neck of the womb) for examination. The removed cells are checked for abnormalities. If abnormal cells are not treated, they may turn into cancer of the cervix, so this test can help prevent cancer.

WHY IS IT DONE IN THE OASIS STUDY?

To adequately evaluate the safety of the study medication, your study doctor needs to be sure that there are no abnormalities in your cervix when you start the study.

HOW IS IT DONE?

A cervical smear is done in your study doctor's office without anesthesia. You will be placed with your feet in stirrups. Your study doctor will insert a speculum into the vagina to hold it open so that your cervix can be viewed. Using a soft brush, the study doctor will take a small sample of cells from your cervix. The cells will then be sent to a pathologist for analysis.

HOW LONG WILL IT TAKE?

The procedure should take less than 5 minutes.

WHAT ARE THE RISKS?

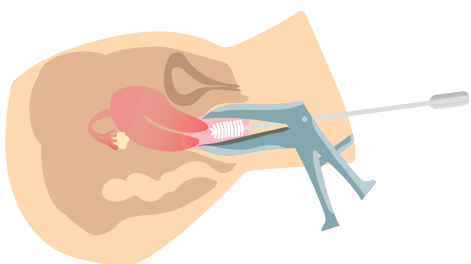
The smear test is a safe, routine procedure. Some women might have vaginal spotting or light bleeding afterward.

What to expect during/after the procedure?

The test usually causes no pain or only mild discomfort. You may have some spotting or light bleeding afterward. This is very common and should go away after a few hours.

You should contact your study doctor if you notice any of the following:

- heavy bleeding after the smear test
- any bleeding after cervical smear that does not stop after a few hours



Mammogram

WHAT IS IT?

A mammogram is an X-ray picture of the breast to look for early signs of breast cancer. Regular mammograms are used to detect breast cancer early, sometimes several years before it can be felt.

WHY IS IT DONE IN THE OASIS STUDY?

To adequately evaluate the safety of the study medication, your study doctor needs to be sure that there are no abnormalities in your breasts when you start the study.

HOW IS IT DONE?

You will stand in front of a special X-ray machine. Your breast will be placed on a plastic plate. Another plate will firmly press your breast from above. The plates will flatten the breast, holding it still while the X-ray is being taken, and the steps are repeated to make a side view of the breast. The other breast will be X-rayed in the same way.

HOW LONG WILL IT TAKE?

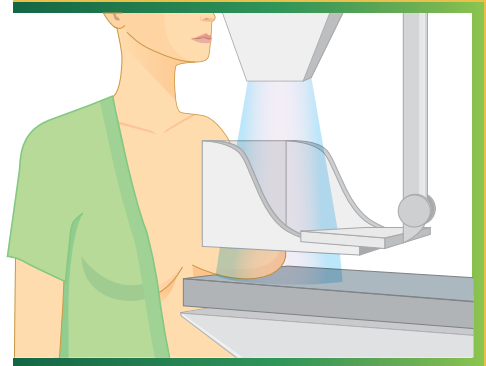
The mammograms should take less than 5 minutes.

WHAT ARE THE RISKS?

Mammograms use a very low level of radiation. Compared to the constant background radiation in the world that we are exposed to every day, the radiation dose from a mammogram is equal to about two months of background radiation for the average woman. For most women, the benefits of regular mammograms outweigh the risks posed by this amount of radiation.

What to expect during/after the procedure?

Having a mammogram is uncomfortable for most women, and some women find it painful. The experience depends on the sensitivity and size of the breasts and how much they need to be pressed. However, since a mammogram takes only a few moments, the discomfort is over soon.



Blood Sampling

WHAT IS IT?

A blood sample will be taken for routine lab tests at every in-person visit at your study site.

WHY IS IT DONE IN THE OASIS STUDY?

Samples will be used to determine your hormone levels to confirm your postmenopausal status or to check your general health, e.g., the function of your liver or to count the cells in your blood. Other samples will look at how the study drug works in your body and how your body affects the study drug.

Blood sampling is also done to perform genetic tests. You can decide if you want your samples to be used for these tests or not. This will not affect your participation in the study. Genetic tests may play an essential role in finding out the reasons and preconditions for a disease or condition.

HOW IS IT DONE?

Blood is drawn from a vein, usually in the arm or hand. The vein is close to the skin and doesn't have many large nerves positioned close by. This reduces pain and discomfort for the patient.

Your study doctor will collect up to 40 ml of blood at each of these visits. That is equal to approximately three tablespoons. In comparison, if you are donating blood, approximately 500 ml are drawn at once.

What to expect during/after the procedure – what are the risks?

You might feel a certain discomfort during blood sampling (pain when the needle is inserted), and you might feel faint and dizzy.

Hematoma/bruising or light bleeding may occur at the puncture site.

Infections on the puncture site are very rare due to careful disinfection.



Pregnancy Test

WHAT IS IT?

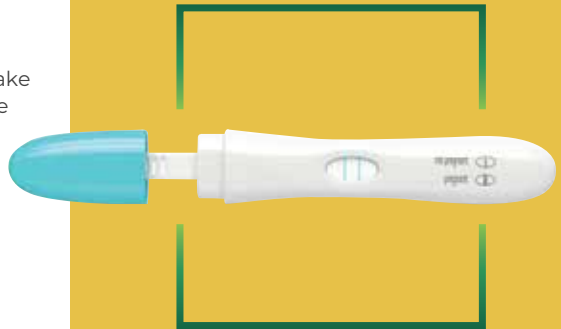
A pregnancy test (Clear blue test) consists of checking your urine for a hormone called human chorionic gonadotropin (HCG). Your body only produces this hormone if you are pregnant.

WHY IS IT DONE IN THE OASIS TRIAL?

Pregnant women cannot participate in the OASIS trials, so your study doctor needs to make sure you are not pregnant before entering the study. If menopause has been confirmed, the test is not required.

HOW IS IT DONE?

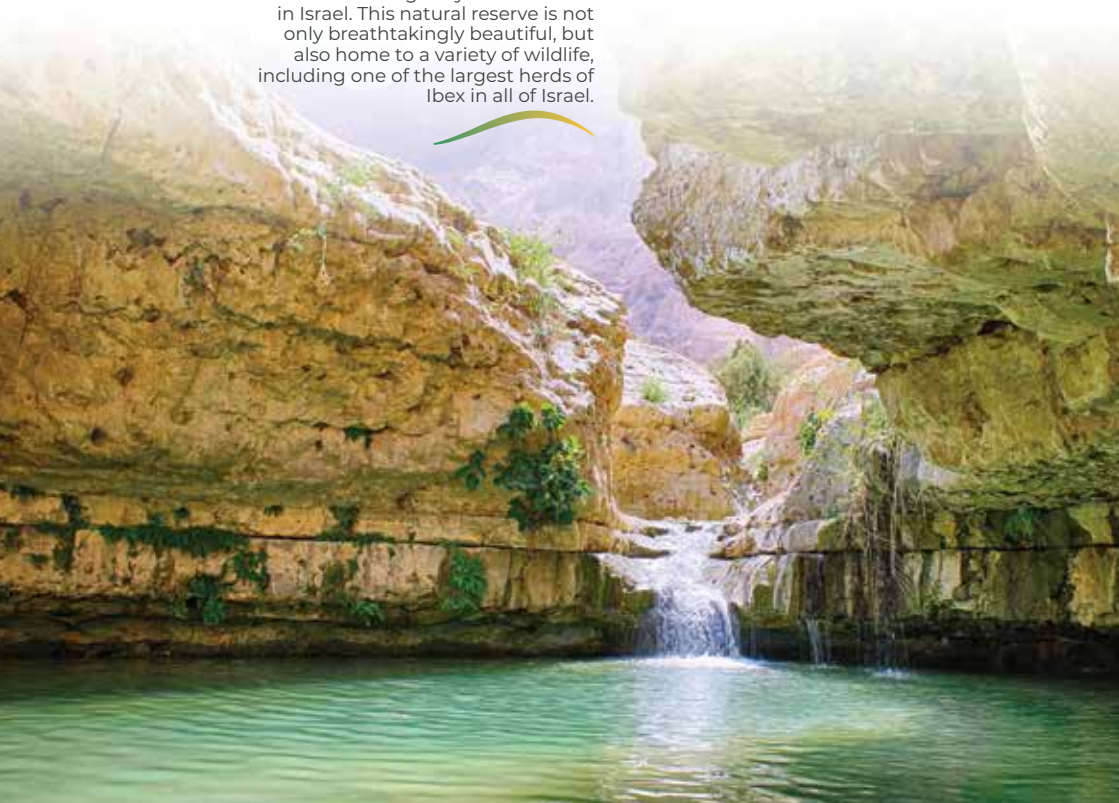
- 1 Remove the test stick from the wrapper and take off the cap.
- 2 Place the absorbent tip in your urine stream for 5 seconds. Or, if you prefer, dip into a urine sample collected in a clean, dry container for 5 or 20 seconds, depending on the test you're using.
- 3 Keep the absorbent tip pointing downwards throughout the testing process – i.e., never turn the stick with the absorbent tip pointing upwards.
- 4 Replace the cap and lay the stick flat.
- 5 Wait for 1 – 3 minutes according to the instructions for the test you are using.
- 6 Read the results. Your study doctor will be able to clarify any questions you might have.



YOUR PARTICIPATION

EIN GEDI, ISRAEL

Ein Gedi means “spring of the kid” and is located right by the Dead Sea in Israel. This natural reserve is not only breathtakingly beautiful, but also home to a variety of wildlife, including one of the largest herds of Ibex in all of Israel.



Your Daily Diary

WHAT IS IT?

The Electronic Diary (eDiary) is a handheld device that looks like a smart phone but can be used only for answering study questionnaires and recording your daily study drug intake. It is a crucial tool to collect information on your health condition, study treatment, and the way you are feeling. We need this information to learn if the study drug works on symptoms of menopause. Keeping accurate records will require some effort from you, but it's crucial to the study's success that you record all information as accurately as possible.

WHY IS IT DONE IN THE OASIS TRIAL?

Your responses to the questions on the diaries will be used to determine if this new study drug will be effective for women with hot flashes. To ensure we capture high-quality data, your answers must be as accurate and consistent as possible.

HOW IS IT DONE?

For this study, you will be asked to complete the diary every day. This may include a short diary to complete twice a day, once in the morning after you wake up, and a second time in the evening right before bedtime; this will only take about 5 minutes to complete. In addition, on certain days during the study, you will need to complete more extensive questionnaires, which will take about 30 minutes.

Your Daily Diary

Here are a few reminders and tips to help you complete the eDiary.

- It is very important to complete the eDiary twice a day when requested, once in the morning upon waking and then once in the evening before bedtime.
- There are no right or wrong answers. Do not exaggerate or underestimate your symptoms. It is important to answer each question as honestly as possible, including your study drug intake. If you didn't take your study drug, report that in your eDiary.
- Always keep the handheld device on and the battery charged.
- Remember to always bring the handheld device with you to the study site. Please take the handheld device and charger with you when traveling.
- Your responses won't be saved until you click "OK" and "Next" on the final screen.

Lastly, please contact the study site right away if you have any questions about the study or have problems using the handheld device. It is important to resolve any questions or problems as soon as possible. Please see the "Participant quick guide for the electronic handheld device" provided by your site for more information.

UMM AL-MA LAKE, LIBYA

The idyllic oasis of Umm al-Ma Lake is located in the Awbari Sand Sea within the Sahara Desert of Libya. The name Umm al-Ma translates to "Mother of Waters".

Compliance Matters

WHY YOU MUST COMPLETE THE eDIARY DAILY THE RIPPLE EFFECT

Completing the eDiary should become routine for you, like brushing your teeth before going to bed and after getting up. We would like to motivate you to complete the eDiary every single day until you will have finished the study. Why?

Think of yourself as a drop of water. You fall into a lake, a sea, an ocean. Although not noticeable, the effects of a single drop of water could cause ripples significant enough to cause a wave!

You are this drop of water. You are the center and the reason why the study is being conducted. All your contributions matter. Each response you enter into the eDiary is crucial in assessing whether the study medication you are taking is well-tolerated, safe, and effective. The study you are participating in is one of several studies determining whether the new investigational drug can be submitted to competent Health Authorities. If the Health Authority approves the medication, it will become available for all patients to receive; and you, along with countless others, might benefit from it.

And think of all the drops of water which fell before you?

This is the reason why your daily completion of the eDiary counts. **YOU COUNT!**



Your Opinion Matters



**YOUR FEEDBACK
IS IMPORTANT**

It is important to Bayer that your voice continues to be heard, especially during your participation in the OASIS clinical study. You will have the opportunity to provide confidential feedback on your experience multiple times by taking a survey. Your study doctor's team will provide you with this opportunity during your Baseline Visit and Study Treatment Visit 3, as well as when you end the study. You can also choose to take the feedback survey online.

**Thank you for participating
in the OASIS study!**

Site Information



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