Women's Health Study for FSAD

Frequently Asked Questions

Female sexual arousal disorder (FSAD) is a common condition that makes it difficult for women to reach or maintain a sufficient physical response to sexual stimulation. If you suspect you have FSAD, you may qualify to participate in a new clinical research study. The study is for an investigational cream intended to treat FSAD and used in the privacy of your home.

1. What is the purpose of a clinical study?

Clinical studies (also called clinical trials) are used to learn about the safety and effectiveness of new medications, medical devices, and medical procedures. Although there are many types of clinical trials, all must conform to strict rules set by the U.S. Food and Drug Administration (FDA). These rules help protect the rights and safety of those who volunteer to take part in clinical trials.

2. How many women will participate in the study?

The study will enroll up to 590 women at 50 - 60 study centers across the United States. Your partner will also participate in some aspects of the study.

3. Will I have to pay for anything if I choose to participate in the study?

Participants in the study will receive all study-related care and study medication at no cost. You will also be compensated up to $800 for your time and travel to attend required study visits.

4. Does everyone in the study receive the investigational cream?

No. Study participants will be randomly assigned (by chance) to use either the investigational cream (50% chance) or a placebo cream (50% chance). The placebo cream looks just like the investigational cream, but has no active ingredient. Neither you nor your doctor will know which cream you receive. This is a common technique in clinical studies, as it helps doctors and researchers understand the effects of the investigational medication without bias.

5. How long does the study last?

The study lasts about 5 months. During this time, you will meet with your study doctor up to 7 times. These visits are an important part of the study, as they allow your study doctor to monitor your health and FSAD symptoms, as well as discuss your overall experience. Your partner will join you at 3 of these visits to meet with the study doctor and answer health-related questions.

6. What happens during the visits?

During your first two visits (approximately 1 week apart), your study doctor and staff will review your symptoms and medical history to confirm if you are eligible to join the study. You will also receive a routine pelvic exam at each visit.

If you are eligible and choose to participate, you will return one month later to receive the study medication to be used at home. You will then return to your study doctor's office once a month over the next 4 months. During these visits your study doctor will perform standard pelvic exams and you will complete questionnaires about your health. Before you decide to participate, your study team will provide you with a detailed summary of what will happen at each visit, so that you can make an informed decision about joining the study.

7. What if I join the study and decide I do not want to participate anymore?

As with all clinical studies, your participation is completely voluntary. You may leave the study at any time without any effect on your future medical care.

8. I am interested in possibly moving forward. What is the next step?

Please contact your local study center, and they will work with you to schedule a convenient time for your initial visit.

Thank you for your interest in our study. Please do not hesitate to contact us with any questions!