

ALISTA

Participant Newsletter

➔ Your guide to the ALISTA clinical study.

► How is the ALISTA clinical study designed?

The ALISTA clinical study is designed to evaluate the safety and effectiveness of topically applied alprostadil prostaglandin E₁, ALISTA, a for the treatment of hysterectomized women with Female Sexual Arousal Disorder (FSAD). All of the women in the study are between 21 and 60 years of age, have undergone a hysterectomy, have been diagnosed with FSAD, and are in a stable, monogamous heterosexual relationship. You and the other study participants have been randomly assigned into one of two treatment groups. Both groups have been given a topical solution to apply prior to sexual activity. One group has received the topical solution containing 400 mcg of alprostadil. The other group has received a placebo, which is a treatment that appears the same as the active solution but does not contain the active drug. Placebos are used in clinical studies to provide a similar comparison group so that the active drug's true effectiveness can be determined.

► Benefits of participating in a clinical trial

As a participant in this important study, you will receive free medical evaluations. You will also receive the investigational medication or placebo free of charge for the duration of the study. Although treatments may improve the ability to become sexually aroused, not all patients participating in this study will receive the active drug, and ALISTA may not be effective for all who do receive it. More importantly, you will have the benefit of knowing that your continued participation in this study will help to advance scientific knowledge on FSAD—and that this research may help to make ALISTA available to women suffering from FSAD in the future.

► Rekindling the Romance

By participating in the ALISTA clinical study, you're showing a strong commitment to achieving sexual satisfaction with your partner. But sexuality is just one component of a successful, happy relationship. As a partner in a long-term monogamous relationship, here are some ways you can rekindle the romance you felt early in your courtship:

- Take a vacation alone with your partner. Talk to each other to mutually determine the elements of your perfect romantic getaway and then make it happen.
- Set a weekly date night without distractions for just the two of you. Don't be afraid of ruining the spontaneity with planning. People like to think of the beginning of their courtship as filled with spontaneity, but it was really a time when you planned things out and were on your best behavior to impress your future mate.
- Remind your partner that you care. Say "I Love You," send e-mails expressing your affection, leave a Post-It note for your partner on the door that'll surprise them in the morning. For an added touch, mail them a handwritten love letter.
- Keep communication open and honest—and keep your promises. The foundation of a great relationship is trust.
- Exchange a list with your partner of the things you enjoy that your partner does for you. Remind each other why you fell in love with one another.
- Surprise your partner with an act they won't expect but will appreciate.
- Share your dreams for the future and really listen to each other.



By acting on these tips and by finding your own ways to be romantic, you can rekindle the romance in your relationship that may have disappeared in the midst of your hectic, responsibility-filled lives. In truth, most tips about how to be more romantic center around three core ideas: make time to be alone together, really communicate with one another, and constantly remind your partner that you care.



A Conversation with Dr. James Simon

Dr. Simon is a Clinical Professor of Obstetrics and Gynecology at George Washington University in Washington, D.C and is also Medical Director of the Women's Health Research Center in Laurel, Maryland. He is one of the physicians participating in the ALISTA clinical study.

What makes lack of arousal different than lack of desire?

Desire is interest in sex. Women with desire disorder commonly complain that sexual thoughts just never enter their mind. Arousal disorder is when a woman may have plenty of sexual thoughts or even overt sexual desire but seems incapable of becoming aroused. This lack of arousal includes an inability of the clitoris and labia to engorge and the vagina to lubricate. The cause of lack of desire is mostly related to a decrease in testosterone, estrogen, or both; arousal problems occur because of physical damage to the nerves and particularly the blood vessels leading to a reduction of blood flow to the genital organs. This situation occurs commonly following a hysterectomy.

How common is female sexual arousal disorder (FSAD)?

FSAD is relatively common, particularly in women who've had hysterectomy. About one in five women report that they frequently have trouble getting aroused. Three-quarters of those women are menopausal, most of them surgically menopausal.

What are the most common symptoms of FSAD?

The most common symptoms are lack of vaginal lubrication, decrease in clitoral and labial sensation, decreased clitoral and labial engorgement at the time of sexual excitement, and decreased excitement. If these symptoms lead to distress, we label it female sexual arousal disorder. If the symptoms occur in women who aren't sexually active or don't have a desire to change the situation, we don't consider



them to have the diagnosis since it's only considered a disorder if the person perceives the condition to be a problem.

Is there anything else that current study participants should know?

Yes. It's great that the women reading this are in the study, but if they know other individuals who are suffering from FSAD, it would be helpful if they could inform them about the study as well. To fully evaluate the efficacy of this drug—and possibly provide an eventual treatment for FSAD—we need to test ALISTA with a substantial number of participants.

IN THE NEWS

December 2004



Procter & Gamble withdrew its application to the Food and Drug Administration (FDA) for its investigational testosterone patch for female sexual dysfunction (FSD). The decision to withdraw the product's submission came after a panel of outside reproductive-health experts voted unanimously against the FDA approving the patch, questioning the length and size of the clinical studies conducted for the drug. Procter & Gamble said it is planning to conduct additional trials so that it may submit a new application in the future.

Testosterone treatments as well as estrogen therapies are types of hormonal therapies, which attempt to address the issues of female sexual *desire*. To address female sexual *arousal* problems, drug companies are testing non-hormonal therapies such as versions of the vasodilator therapies currently available on the market to treat male sexual arousal problems. The prescription drugs Viagra and Cialis have already been clinically tested on women but were found to be ineffective. Alprostadil, which is also used to treat sexual dysfunction in men, is the key ingredient in ALISTA and has shown promise in treating female sexual arousal disorder (FSAD).

How to Get Your Questions Answered

If you have any questions, please contact your study doctor or clinic staff.