A study to investigate the efficacy of sublingual testosterone solution on physiological and subjective arousal in healthy, sexually dysfunctional premenopausal women.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23272

Source
Nationaal Trial Register

Brief title
PD Testosterone

Health condition

Female sexual dysfunction (FSD),Female Sexual Arousal Disorder, Hypoactive sexual desire disorder, sublingual testosterone

Sponsors and support

Primary sponsor: Emotional brain BV
Source(s) of monetary or material Support: Emotional brain BV

Intervention

Outcome measures

Primary outcome

To confirm the lack of effect of sublingual testosterone on physiological and subjective measures of sexual arousal in women with Hypoactive Sexual Desire Disorder (HSDD).

Secondary outcome

To confirm the lack of effect of sublingual testosterone on physiological and subjective measures of sexual arousal at three post dose time points.

Study description

Background summary

In 2 arms, a total of 16 subjects receive each investigational drug separately and are separated by a 48 hour washout period. The order in which subjects undergo the 2 doses of medication is randomized. There are two experimental days (psychophysiological measurements). During the 2 experimental days, subjects receive placebo, or testosterone sublingually in random order. Subjects visit the site a total of 4 times: 1 screening visit, 2 experimental days, and 1 final follow up visit.

Study objective

This present study is a pharmacodynamic study of which the main goal is to confirm the lack of effect of testosterone sublingual alone in 16 premenopausal sexually dysfunctional healthy women using physiological and subjective measures of sexual arousal at four different time points.

An earlier study reported that about three to four and a half hours after administration of sublingual testosterone a peak was seen, and we found a striking increase in vaginal responsiveness when the subjects were exposed to the visual sexual stimuli. These findings demonstrate a time lag in the effect of sublingually administered testosterone on genital arousal in sexually functional women. This study was replicated 2 years later with the same results (Tuiten et al., 2002).

In these two previous studies only sexually functional women participated. For women with Female Sexual Dysfunction, sublingual testosterone alone is not sufficient (van der Made et al, 2009). This study showed a slightly increase in VPA for testosterone alone, although not significant. But the condition sublingual testosterone combined with vardenafil (a PDE-5

inhibitor) showed a strong, significant, increase in VPA, as compared to placebo, vardenafil and testosterone alone. The same results, a slight increase with testosterone alone and a high increase with testosterone combined with vardenafil, were found in a second study with sexually dysfunctional women (van der Made et al, 2009).

Therefore the hypothesis are:

1. Testosterone will not increase VPA in response to erotic film excerpts for sexually dysfunctional premenopausal women, as compared to placebo (pre-dose). This will be tested by rejecting the null hypothesis that the difference between placebo and VPA is outside the equivalence limits -0.45 and 0.45;

2. Testosterone will not increase Sexual Arousal Response Self Assessment Questionnaire (SARSAQ) in response to erotic film excerpts for sexually dysfunctional premenopausal women, as compared to placebo (pre-dose).

Study design

The trial duration is five weeks per subject from screening visit to follow up.

Intervention

One dose of placebo and one dose of testosteron sublingually.

Doses are separated by a 48 hour washout period.

Contacts

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Eligibility criteria

Inclusion criteria

For inclusion in the study, the subjects of the study group healthy women with Female Sexual Dysfunction must fulfill the following criteria:

1. Female 21-40 years of age with Hypoactive Sexual Desire Disorder (comorbidity with other sexual dysfunctions e.g Female Sexual Arousal Disorder (FSAD) is allowed). The diagnosis will be made by an experienced psychologist/sexologist;

2. Healthy according to normal results of medical history, physical examination, laboratory values and vital signs, unless the investigator considers an abnormality to be clinically relevant;

3. Subject must be heterosexually oriented;

4. BMI ≥ 18 and ≤ 30 kg/m2.

Exclusion criteria

1. A history of Childhood Sexual Abuse;

2. Subjects who had used testosterone therapy within 6 months before study entry;

3. (A history of) hormone-dependant malignancy;

4. Use of oral contraception containing anti-androgens (e.g. Diane 35; Minerva);

5. Use of oral contraception containing 50 µg estrogen or more;

6. Pregnancy, or intention to become pregnant during this study (Note: a serum or urine pregnancy test will be performed in all women prior to the administration of study medications);

7. A pelvic inflammatory disease or an untreated vaginal infection at screening;

8. Lactating, or subjects who have given birth in the previous 6 months;

9. Previous prolapse and incontinence surgery affecting the vaginal wall, which in the opinion of investigator would interfere with the VPA measurement;

10. Women with other unexplained gynecological complaints, such as abnormal uterine

bleeding patterns;

11. (History of) endocrine disease;

12. (History of) severe neurological problems, current severe neurological problems, or other mild or moderate neurological problems which in the opinion of investigator would interfere with the participant’s ability to provide informed consent, comply with study instructions, confound interpretation of study results, or endanger the participant if she took part in the trial;

13. Treatment for a current serious psychiatric disorder (e.g., schizophrenia, psychosis) or treatment for obsessive compulsive disorder, anorexia nervosa, bulimia nervosa and/or social anxiety neurosis;

14. Any underlying cardiovascular condition including unstable angina pectoris, that would preclude sexual activity;

15. (History of) myocardial infarction, stroke or life-threatening arrhythmia within the prior 6 months;

16. Uncontrolled atrial fibrillation/flutter at screening (ventricular response rate > 60-80 bpm in rest, > 90-115 bpm in moderate exercise), or other significant abnormality observed on ECG;

17. Systolic blood pressure ≥ 130 mmHg and/or diastolic blood pressure ≥ 80 mmHg;

18. Subjects who are taking CYP3A4-inhibitors: ritonavir (HIV-proteaseremmer), ketoconazol en itraconazol claritromycine, erytromycine and saquinavir;

19. Subjects who are taking CYP3A4-inducers: carbamazepine, fenytoïne, fenobarbital, st Johns Wort, rifampicine;

20. Acute/chronic liver disease: ASAT and ALAT > 3x the upper limit of normal;

21. Renal insufficiency (< 29 ml/min): based on the Cockcroft and Gault formula;

22. A substance abuse disorder that in the opinion of the investigator is likely to affect the subject's ability to complete the study or precludes the subject’s participation in the study; mild or moderately alcohol drinking behavior is allowed, only 24 hours before the experimental days is alcohol drinking not allowed. Three weeks before the start of the experimental day is the taking of any recreational drug not allowed. Smoking is allowed;

23. Subjects who are illiterate, unwilling or unable to understand and complete the questionnaires;

24. Any other clinically significant abnormality or condition which in the opinion of investigator would interfere with the participant’s ability to provide informed consent, comply

with study instructions, possibly confound interpretation of study results, or endanger the participant if she took part in the trial;

25. Subjects with a peri menopausal hormonal status (FSH > 30).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2010
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-05-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2201
NTR-old	NTR2325
Other	Emotional Brain : EB80
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A