A double blind, randomized, cross-over placebo controlled pilot study to investigate the subjective and physiological efficacy and safety of Lybridos in healthy female subjects with Female Sexual Dysfunction.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26110

Source
Nationaal Trial Register

Brief title
Lybridos PoC

Health condition

Female Sexual Dysfunction (FSD), Hypoactive Sexual Desire Disorder (HSDD), Female Sexual Arousal Disorder (FSAD)

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

To evaluate efficacy of Lybridos on physiological and subjective indices of sexual arousal in healthy female subjects with Female Sexual Dysfunction.

Secondary outcome

1. To investigate Lybridos' influence on attentional bias for erotic stimuli;

2. To evaluate the safety of Lybridos.

Study description

Background summary

In 2 arms, a total of 13 subjects receive the investigational drug. During the 2 experimental days (where psychophysiological measurements will take place), subjects receive placebo and Lybridos in random order.
Subjects visit the site à total of 4 times: 1 screening visit, 2 experimental days, and 1 final follow up visit.

Study objective

In the present study we will investigate the efficacy of Lybridos in one group of subjects with FSD in the laboratory. We will measure subjective, physiological and neuropsychological measures of sexual functioning in the Emotional Brain laboratory.

Hypothesis:

1. Lybridos, compared to placebo, significantly increases subjective measures of sexual arousal;

2. Lybridos, compared to placebo, significantly increases genital measures of sexual arousal;

3. Lybridos, compared to placebo, significantly increases attentional bias for sexual cues.

Study design

In 2 arms, a total of 13 subjects receive the investigational drug on one experimental day and

receive placebo on another experimental day.

Intervention

Lybridos (one gift) and placebo (one gift).

Contacts

Public
Emotional Brain bv
K. Rooij, van
Louis Armstrongweg 78
Almere 1311 RL
The Netherlands
+31 (0)36 5468346
Scientific
Emotional Brain bv
K. Rooij, van
Louis Armstrongweg 78
Almere 1311 RL
The Netherlands
+31 (0)36 5468346

Eligibility criteria

Inclusion criteria

Thirteen (13) premenopausal and postmenopausal women with Hypoactive Sexual Desire Disorder (HSDD), with or without Female Sexual Arousal Disorder (FSAD).

Additionally, subjects must meet the following criteria:

1. Subjects must have a heterosexual orientation;

2. Subjects must be between 21 and 70 years of age;

3. Subjects must have experienced low sexual arousal and/or low sexual desire for at least six months prior to study entry according to DSM IV criteria. The diagnosis will be made by an experienced psychologist/sexologist;

4. Subjects must have signed the Informed Consent Form;

5. Inclusion will be following the selection criteria including, but not limited to, a physical examination, gynecological examination, medical history, vital signs, pregnancy test and ECG, and by the scoring on the Stroop task during familiarization trial.

Exclusion criteria

Subjects will not be eligible for inclusion if one of the following criteria applies:

1. Use of oral contraception containing anti-androgens (Like Diane 35 or Minerva);

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

3. 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);

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

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

6. Previous prolapse and incontinence surgery affecting the vaginal wall;

7. Women with other unexplained gynecological complaints, such as abnormal uterine bleeding patterns;

8. History of endocrinological treatment or current endocrinological treatment (with the exception of the use oral contraceptives);

9. 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;

10. History of severe psychiatric problems or current severe psychiatric problems, or other mild or moderate psychiatric 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;

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

12. Renal insufficiency (< 30 ml/min): based on the Cockcroft and Gauld formula;

13. Liver insufficiency: when ASAT or ALAT > 3x normal laboratory values;

14. Uncontrolled atrial fibrillation/flutter at screening (ventricular response rate > 100 bpm), or other significant abnormality observed on ECG;

15. Systolic blood pressure > 140 mmHg and/or diastolic blood pressure > 90 mmHg. For subjects with age > 60 years and without diabetic mellitus, familiar hypercholesterolemia or cardiovascular disease: Systolic blood pressure > 160 mmHg and/or diastolic blood pressure > 90 mmHg (According to the CBO-guideline hypertension (CBO.2000a)). Systolic blood pressure < 90 mmHg and/or diastolic blood pressure <50 mmHg;

16. Subjects who are taking strong CYP3A4-inhibitors: ritonavir (HIV-proteaseremmer), ketoconazol en itraconazol;

17. Subjects who are taking less strong CYP3A4-inhibitors: claritromycine, erytromycine en saquinavir;

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

19. Severe chronic or acute liver disease, history of moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment;

20. Use of medicinal herb as Ginkgo Biloba, St John's wort and nutrition containing grapefruit; avoid valerian, gotu kola, kava kava (may increase CNS depression);

21. Subjects who are taking MAO inhibitors (includes classic MAO inhibitors and linezolid), Calcium channel blockers (e.g. Diltiazem and verapamil), Nefazodone, SSRIs, TCAs, Tramadol;

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 12 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. Use of any treatment for FSD within the 7 days before visit 1 or during the study, including oral medications or constrictive devices;

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

25. 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;

26. Subjects who are experiencing vision impairment, like partial or complete blindness or color blindness;

27. Subjects with a peri menopausal hormonal status;

28. Subjects with a body mass index (BMI)>35 kg/m2.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-01-2009
Enrollment:	13
Type:	Actual

Ethics review

Positive opinion

Date:	21-01-2009
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	NL1558
NTR-old	NTR1637
Other	Emotional Brain : EB 077
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A