@home: a study to investigate the subjective and physiological efficacy and safety of Lybrido and Lybridos in the domestic setting in healthy female subjects with Female Sexual Dysfunction and SSRI usage.

No registrations found.

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

Summary

ID

NL-OMON23989

Source
Nationaal Trial Register

Brief title
@HOME

Health condition

Selective serotonin reuptake inhibitors (SSRIs), Female sexual dysfunction (FSD), Hypoactive sexual desire disorder, Female sexual arousal disorder

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 Lybrido and Lybridos on subjective sexual experience in the domestic setting in healthy female subjects Female Sexual Dysfunction using SSRIs.

Secondary outcome

1. To evaluate efficacy of Lybrido and Lybridos on physiological sexual responding (vaginal and clitoral) in the domestic setting in different subgroups of women with FSD in combination with SSRI use;

2. To investigate differences in attentional bias for erotic stimuli in different subgroups of women with FSD and SSRI induced FSD, and the influence of Lybrido and Lybridos herein;

3. To investigate differences in subjective, physiological and neuropsychological responding at home or in the laboratory;

4. To evaluate the safety of Lybrido and Lybridos in the domestic setting.

Study description

Background summary

In 3 arms, a total of 40 subjects receive each investigational drug separately for a duration of four weeks. The placebo regime (duration 4 weeks), the Lybrido regime (duration 4 weeks), and the Lybridos regime (duration 4 weeks) are separated by a one- till four-week washout period.
The order in which subjects undergo the 4 week medication regimes is randomized following a Latin Square design.
At the beginning of each medication regime, subjects take home a mobile psychophysiological laboratory for 3 measurements in the domestic setting. The domestic part of the study is preceded by three experimental days (psychophysiological measurements). During the 3 experimental days, subjects receive placebo, Lybrido or Lybridos in random order.
Subjects visit the site à total of 13 times: 2 screening visits, 3 experimental days, 4 safety control visits, 3 regime follow-ups and 1 final follow up visits. During the safety control visits the subject’s health will be monitored and medication is dispensed.

Study objective

In the present study we will investigate the efficacy of Lybrido and Lybridos in one group of

subjects with FSD using SSRIs in the laboratory and in the domestic setting of these subjects. We will measure subjective, physiological and neuropsychological measures of sexual functioning, in the Emotional Brain laboratory and in the homes of the subjects, which enables us to compare different responding to subjective, physiological and neuropsychological measures in these two settings. To this end, we have developed a portable self-operated laboratory which can measure vaginal and clitoral blood flow/volume in response to neutral and erotic film clips, and attention for erotic stimuli.

1. Subjects with SSRI induced FSD will have low attention for sexual stimuli;

2. Subjects with SSRI induced FSD will benefit more from Lybridos compared to Lybrido and placebo;

3. Subjects who already experienced FSD before the usage of SSRIs and have low attention to sexual stimuli will benefit more from Lybrido compared to Lybridos and placebo;

4. Subjects who already experienced FSD before the usage of SSRIs and have high attention to sexual stimuli will benefit more from Lybridos compared to Lybrido and placebo;

5. The attention for sexual stimuli is SSRI dose-related; the higher the dose the lower the attention for sexual stimuli. Subjective and genital measures of sexual arousal will be significantly larger at home compared to the laboratory on site.

Study design

The trial duration is 22 weeks, of which 12 weeks medication is dispensed.

Measurements:

1. Subjective ratings of sexual functioning (questionnaires & diaries);

2. Attention for erotic stimuli (Stroop task);

3. Vaginal Pulse Amplitude (VPA);

4. Clitoral Blood Volume (CBV);

5. Personality traits;

6. History of negative sexual experiences.

Intervention

Lybrido, Lybridos and placebo.

The placebo regime (duration 4 weeks), the Lybrido regime (duration 4 weeks), and the Lybridos regime (duration 4 weeks) are separated by a one- till four-week washout period.

Contacts

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Eligibility criteria

Inclusion criteria

1. Provision of written informed consent;

2. Female 21 – 70 years of age with Hypoactive Sexual Desire Disorder (comorbidity with other sexual dysfunctions e.g Female Sexual Arousal Disorder (FSAD) is allowed) and/or SSRI induced sexual dysfunctioning. The diagnosis will be made by an experienced psychologist/sexologist;

3. Usage of a SSRI for at least 3 months;

4. The SSRI must be on a stable dose for at least 6 weeks;

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

6. Subjects must have a heterosexual relationship.

Exclusion criteria

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, which in the opinion of investigator would interfere with the VPA measurement;

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

8. Childhood sexual abuse before the age of 16 (CSA as defined by the decision tree in Appendix 4);

9. PTSS as a result of sexual abuse (using the M.I.N.I plus 5.0.0 questionnaire);

10. History of endocrine disease;

11. 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;

12. 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;

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

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

15. 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;

16. 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;

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

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

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

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

21. 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);

22. Subjects who are taking nitrates or nitric oxide donors;

23. Subjects who are taking MAO inhibitors (includes classic MAO inhibitors and linezolid), Calcium channel blockers (e.g. Diltiazem and verapamil), Nefazodone, Trazodon, TCAs, tramadol, lithium, pethidin, any medicine belonging to the triptans (i.e. sumatriptan);

24. 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;

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

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

27. 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;

28. Subjects who do not have easy access to a/their partner (for example because the partner works on a drilling platform at sea);

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

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

31. Subjects who do not have easy access to the internet;

32. Subjects with a peri menopausal hormonal status;

33. Clinical suspicion of carcinoid syndrome (spells of flushing, diaphoresis and abdominal cramps);

34. History of serotonin syndrome.

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):	01-01-2010
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-01-2010
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	NL2041
NTR-old	NTR2158
CCMO	NL30274.040.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A