

@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

No registrations found.

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

Summary

ID

NL-OMON28613

Source

NTR

Brief title

@HOME

Health condition

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

Sponsors and support

Primary sponsor: Emotional Brain

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

Intervention

Outcome measures

Primary outcome

To evaluate efficacy of Lybrido and Lybridos on subjective sexual experience in the domestic setting in healthy female subjects with Female Sexual Dysfunction.

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.
2. To investigate differences in attentional bias for erotic stimuli in different subgroups of women with 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 120 subjects (4x30) 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: 1 screening, 3 experimental days, 5 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 two subgroups

of subjects with FSD 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.

Lybrido, compared to placebo and Lybridos, significantly increases subjective and genital measures of sexual arousal in women with initially low attention for sexual stimuli.

Lybridos, compared to placebo, significantly increases subjective and genital measures of sexual arousal in women with initially low attention for sexual stimuli.

Lybridos, compared to placebo and Lybrido, significantly increases subjective and genital measures of sexual arousal in women with initially high attention for sexual stimuli.

Pre- and post menopausal women do not differ in any of the subjective and genital measures of sexual arousal, in all medication conditions in both settings.

Subjective and genital measures of sexual arousal will be significantly larger at home compared to the laboratory on site.

Study design

In 3 arms, a total of 120 subjects (4x30) receive each investigational drug separately for a duration of four weeks.

The periods are separated by a one- till four-week washout period.

Intervention

Lybrido, Lybridos and placebo for 1 year.

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 fulfil the following criteria:

1. Provision of written informed consent.
2. Female heterosexual 21 - 70 years of age with Hypoactive Sexual Desire Disorder and/or Female Sexual Arousal Disorder for at least six months prior to study entry.
3. Being either premenopausal (sixty subjects) or postmenopausal (sixty subjects).
4. Scoring either high or low for attention for sexual stimuli at the screening.
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.

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.
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 and of fertility-promoting treatment).
9. History of neurological treatment or current neurological treatment.

10. History of serious psychiatric treatment or current psychiatric treatment.
11. Any underlying cardiovascular condition including unstable angina pectoris, that would preclude sexual activity.
12. History of myocardial infarction, stroke or life-threatening arrhythmia within the prior 6 months.
13. Uncontrolled atrial fibrillation/flutter at screening (ventricular response rate > 100 bpm), or other significant abnormality observed on ECG.
14. 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
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15. Subjects who are taking strong CYP3A4-inhibitors: ritonavir (HIV-proteaseremmer), ketoconazol en itraconazol.
16. Subjects who are taking less strong CYP3A4-inhibitors: claritromycine, erytromycine en saquinavir.
17. Subjects who are taking CYP3A4-inducers: carbamazepine, fenytoïne, fenobarbital, st Johns Wort, rifampicine.
18. Severe chronic or acute liver disease, history of moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment.
19. 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).
20. Subjects who are taking nitrates or nitric oxide donors.
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 do not have easy access to a/their partner (for example because the partner works on a drilling platform at sea).

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

28. Subjects with a peri menopausal hormonal status.

29. Subjects who do not have easy access to the internet.

30. 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): | 12-02-2008 |
| Enrollment: | 120 |
| Type: | Actual |

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 17-03-2008

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 | NL1183 |
| NTR-old | NTR1228 |
| Other | Emotional Brain : EB070 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

Study results

Summary results

N/A