@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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28613

Bron
NTR

Verkorte titel
@HOME

Aandoening

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

Ondersteuning

Primaire sponsor: Emotional Brain
Overige ondersteuning: Emotional Brain

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Lybrido, Lybridos and placebo for 1 year.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	12-02-2008
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-03-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1183
NTR-old	NTR1228
Ander register	Emotional Brain : EB070
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A