A study to validate the demarcation formula for Lybrido and Lybridos

No registrations found.

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

Summary

ID

NL-OMON28721

Source
Nationaal Trial Register

Brief title
CD001

Health condition

FSIAD

Sponsors and support

Primary sponsor: Companion Diagnostics BV
Source(s) of monetary or material Support: Companion Diagnostics BV

Intervention

Outcome measures

Primary outcome

• The primary endpoint is the change from placebo in frequency of satisfactory sexual events, following study medication intake, measured by the Sexual Event Diary (SED), item 4 (this endpoint is used for both the primary and secondary objective above)

Secondary outcome

3.3.2 Exploratory Endpoints

• Change from placebo in experienced sexually-related personal distress, measured by the Female Sexual Distress Scale-Revised (FSDS-R), specifically item 13.

• Evaluation of meaningful improvement during treatment period, measured by the single item Patient's Global Impression of Improvement (PGI-I)

• Evaluation of meaningful benefit of study medication during treatment period, measured by the single item Patient Benefit Evaluation (PBE)

• Change from placebo in frequency of orgasms, following medication intake, measured by the SED

• Change from placebo in sexual desire, following medication intake, measured by the SED

• Change from placebo in physical arousal, following medication intake, measured by the SED

• Change from placebo inmental arousal, following medication intake, measured by the SED

• Change from placebo in sexual pleasure, following medication intake, measured by the SED

3.3.3 Safety evaluation

• Adverse events

• Physical examination (including vital signs)

• Signs of hyperandrogenism

• Laboratory assessments (including blood chemistry, hematology and hormone levels)

Study description

Study objective

2.2.1 Validation of existing demarcation formula
In the present study, the existing demarcation formula will be validated. Its predictive power for Lybrido and Lybridos sensitivity will be measured using the subjects number of satisfying sexual events on Lybrido and Lybridos as compared to Placebo in the domestic setting in 150 healthy female subjects with FSIAD.

• Women with a low sensitivity (as compared to high sensitivity) for sexual cues as

determined by the present demarcation formula will have a statistically significant higher number of satisfying sexual events in the Lybrido regime as compared to the placebo and Lybridos treatments;

• Women with a high sensitivity (as compared to low sensitivity) for sexual cues as determined by the present demarcation formula, will have a significantly higher number of satisfying sexual events in the Lybridos regime as compared to the placebo and Lybrido regimes.

2.2.2 Testing of altered demarcation formula
The demarcation formula could be altered and improved with new biological markers using essentially the same iterative process as described in section 2.1.5.2, using the first 75 subjects who complete this study. This altered demarcation formula will be tested in the second set of 75 subjects who complete the study, in the same way as the existing demarcation formula is validated above.

2.2.2.1 Primary hypotheses explorative part

• Women with a low sensitivity (as compared to high sensitive women) for sexual cues - as determined by the renewed demarcation formula - will have a higher number of satisfactory sexual events during treatment with Lybrido as compared with Placebo and Lybridos;

• The other way around, women with a high sensitivity (as compared to low sensitive women) for sexual cues will have a higher number of satisfactory sexual events during treatment with Lybridos as compared with Placebo and Lybrido;

Moreover,

• Women with a low sensitive system for sexual cues as determined with the new demarcation formula, will have a higher number of satisfactory sexual events during treatment with Lybrido in comparison with placebo and Lybridos, than women with a low sensitive system established by the original formula;

• Women with a high sensitive system for sexual cues as determined with the new demarcation formula, will have a higher number of satisfactory sexual events during treatment with Lybridos in comparison with placebo and Lybrido, than women with a high sensitive system established by the original formula.

Study design

End of study

Intervention

Placebo, Lybrido (sublingual testosterone + oral sildenafil), Lybridos (sublingual testosterone + oral buspirone) intake at home (on demand); report sexual events; blood draw.

Contacts

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Eligibility criteria

Inclusion criteria

1. Provision of written informed consent;

2. Females between 18 and 70 years of age, inclusive, pre or postmenopausal, with FSIAD (comorbidity with female orgasmic disorder [FOD]; only as secondary diagnosis) is allowed. The diagnosis of FSIAD will be established by a trained health care professional;

3. Be involved in a stable, communicative, monogamous relationship and have a sexually functional partner who will be at home for the majority of the study duration;

4. Healthy with normal medical history, physical examination, laboratory values, and vital signs; exceptions may be made if the investigator considers an abnormality to be clinically irrelevant;

5. Use of highly effective contraception.

Exclusion criteria

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

2. Systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg (supine blood pressure). For subjects ≥ 60 years old and without diabetes mellitus, familial hypercholesterolemia, or cardiovascular disease: systolic blood pressure ≥ 160 mmHg and/or diastolic blood pressure ≥ 90 mmHg;

3. Systolic blood pressure ≤ 90 mmHg and/or diastolic blood pressure ≤ 50 mmHg (supine blood pressure);

Gynecological and Obstetric Conditions

4. Use of any contraceptive containing anti-androgens (e.g. Cyproteron acetate) or (anti)androgenic progestogens (drospirenone, dienogest, chlormadinone acetate and norgestrel);

5. Use of any contraceptive or hormone replacement therapy (HRT) containing more than 50 µg/day of estrogen;

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

7. Lactating or delivery in the previous 6 months prior to signing Informed Consent Form;

8. History of bilateral oophorectomy;

9. Other unexplained gynecological complaints, such as clinically relevant abnormal uterine bleeding patterns;

10. Perimenopausal status (cycle shortening/irregular menstrual bleeding in the last 12 consecutive months and/or occurrence of vasomotor symptoms (e.g. hot flashes, night sweating) and/or FSH levels (>40 IU/L) for women from age 40 onwards; in women with a history of hysterectomy perimenopausality can be assessed by FSH levels (> 40 IU/L) and/or vasomotor symptoms);

Other Medical Conditions

11. Liver and/or renal insufficiency (aspartate aminotransferase, alanine aminotransferase and gamma glutamyltransferase > 3 times the upper limit of normal and/or estimated glomerular filtration rate (eGFR) < 60.00 mL/min based on the Cockcroft Gault formula);

12. Any current endocrine disease or endocrinopathy (e.g. uncontrolled thyroid function) as determined by medical history, basic physical examination and/or laboratory values significantly outside normal range of the central laboratory; or uncontrolled diabetes mellitus(HbA1c > 7.5%);

13. Free- and/or total testosterone levels outside the upper limit of the reference range of the central laboratory;

14. Any current clinically relevant neurological disease which, in the opinion of the investigator, would compromise the validity of study results or which exclude from use of sildenafil, buspirone and/or testosterone;

15. History of hormone dependent malignancy (including all types of breast cancer);

16. Positive test result for immunodeficiency virus, hepatitis B, or hepatitis C (acute and chronic hepatitis infection);

Psychological/Psychiatric Factors

17. History of (childhood) sexual abuse that, in the opinion of the investigator, could result in negative psychological effects when testosterone is administered;

18. (Psychotherapeutic and/or pharmacological treatment for) a psychiatric disorder (other than those under inclusion criterion 6) that, in the opinion of the investigator, would compromise the validity of study results or which could be a contraindication for sildenafil, buspirone and/or testosterone use;

19. Current psychotherapeutic treatment for female sexual dysfunction;

20. Current genito-pelvic pain/ penetration disorder according to the Diagnostic and Statistical Manual of Mental Disorders, fifth edition (DSM 5);

21. 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;

Concomitant Medications

22. Use of potent CYP3A4 inhibitors (eg, ritonavir, ketoconazole, itraconazole clarithromycin, erythromycin and saquinavir);

23. Use of potent CYP3A4 inducers (eg, carbamazepine, phenytoin, phenobarbital, St John’s wort, rifampin);

25. Use of antidepressants including SSRIs, tricyclic and other;

26. Use of any other medication that interferes with study medication (eg, triptans, monoamine oxidase [MAO] inhibitors [includes classic MAO inhibitors and linezolid] and spironolactone);

27. Use of medication (including herbs) that would compromise the validity of study results;

28. Use of testosterone therapy within 6 months before study entry prior to signing the Informed
Consent Form;

General

30. Illiteracy, unwillingness, or inability to follow study procedures;

31. Participation in other clinical trials within the last 30 days;

32. Any other clinically significant abnormality or condition which, in the opinion of the investigator, might interfere with the participant’s ability to provide informed consent or comply with study instructions, compromise the validity of study results, or be a contraindication for buspirone, and/or sildenafil and/or testosterone use.

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):	28-01-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40620
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4282
NTR-old	NTR4426
CCMO	NL44803.056.13
OMON	NL-OMON40620

Study results