A randomised, double-blind, placebo-controlled, parallel group, single centre study investigating the brain processing of visual stimuli in pre-menopausal women with generalized acquired hypoactive sexual desire disorder after 8 weeks of flibanserin (100 mg) treatment.

Published: 04-02-2010
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Change from baseline in regional cerebral blood flow in response to various visual stimuli ascertained by Positron Emission Tomography scan after 8 weeks of flibanserin 100 mg treatment.

Ethical review	Not approved
Status	Will not start
Health condition type	Sexual dysfunctions, disturbances and gender identity disorders
Study type	Interventional

Summary

ID

NL-OMON34777

Source
ToetsingOnline

Brief title
PET scan study

Condition

- Sexual dysfunctions, disturbances and gender identity disorders

Synonym
HSDD, Hypoactive Sexual Desire Disorder

Research involving
Human

Sponsors and support

Primary sponsor: Boehringer Ingelheim
Source(s) of monetary or material Support: Boehringer Ingelheim

Intervention

Keyword: flibanserin, HSDD, PET-scan, VSS

Outcome measures

Primary outcome

Change from baseline in regional cerebral blood flow in response to various

visual stimuli ascertained by Positron Emission Tomography scan after 8 weeks

of flibanserin 100 mg treatment.

Secondary outcome

none

Study description

Background summary

The prevalence of HSDD worldwide is about 10-20%. The aetiology is unknown: there are no clear psychological or physical causes.

Study objective

Change from baseline in regional cerebral blood flow in response to various visual stimuli ascertained by Positron Emission Tomography scan after 8 weeks of flibanserin 100 mg treatment.

Study design

De study is being performed in the UMCG in cooperation with Boehringer Ingelheim BV (sponsor). The Center for Uroneurology and the departments of Gynaecology and Nucleair Medicine are involved. The study starts February 2010

and ends May 2011.

In total 26 women with HSDD will participate:
13 women will be treated for 8 weeks with flibanserin. The other 13 will receive placebo. The study is randomised and doubleblind.

At Visit 1 in- and exclusioncriteria are determined. At visit 2 patients will have their first PET scan. During the PET scan the patients will watch neutral or erotic film fragments. The night of visit 2 patient begin treatment with studymedication. This will continue for 8 weeks. Visit 3 and 4 are safety visits. At visit 5, after 8 weeks of flibanserin use, the second PET scan takes place. Visit 6 is another safety visit.

Intervention

Medical and sexuological history, bloodpressure and pulse, length and weight, physical exam, blood drawing, urine pregnancytest, PET scan, questionnaires, medication intake.

Study burden and risks

The patients are under medical supervision of kwalilfied staff. Flibanserin has been used by over 7300 people and side effects so far are mild to moderate. The radiation exposure is about twice the background radiation and comparable to medical diagnostic procedures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients must have a primary diagnosis of HSDD, generalized acquired type, according to DSM IV-TR criteria. The current episode of HSDD must be at least 24 weeks in duration at the time of the Screening Visit. Patients with secondary Female Sexual Arousal Disorder and / or Female Orgasmic Disorder are allowed in the trial provided that the patient considers HSDD to be of greatest importance.
2. Patients must be female and 18 years of age or older at the Screen visit.
3. Patients must be in a stable, monogamous, heterosexual relationship that is secure and communicative, for at least 1 year prior to the Screen Visit.
4. Pre-menopausal women per the Stages of Reproductive Aging Workshop (STRAW) criteria
5. Patients must be currently using hormonal contraceptive therapy (subcutaneous, injectable, intra-vaginal or oral contraceptive) for at least 3 months before the Screening Visit and continue to use the method of contraception during the trial. However, if the use of a contraceptive is judged to be a contributing factor to the patient's HSDD, the patient should be excluded from the trial.
6. Patients must be able and willing to give meaningful, written informed consent consistent with International Conference on Harmonisation (ICH) / Good Clinical Practice (GCP) guidelines and local regulations prior to participation in the trial.

Exclusion criteria

1. Patients who meet DSM IV-TR criteria for Sexual Aversion Disorder, Substance-Induced Sexual Dysfunction, Dyspareunia, Vaginismus, Gender Identity Disorder, Paraphilia, or for Sexual Dysfunction Due to a General Medical Condition.
2. Patients who have entered the peri-menopause stage (menopausal transition) or the post menopause stage according to the STRAW criteria
3. Patients with findings at the Screening Visit of pelvic pain, pelvic inflammatory disease, endometriosis, urinary tract or vaginal infection / vaginitis, cervicitis, interstitial cystitis,

vulvodynia, or significant vaginal atrophy.
4. Patients who are pregnant or have been pregnant within the last 6 months prior to the Baseline visit.
5. Patients with a history of any other psychiatric disorders that could impact sexual function, risks patient's safety, or may impact compliance.
6. Patients who have been subject to procedures involving ionizing radiation during the last two years prior to the Screening Visit.
7. Patients who are left-handed.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	26
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	flibanserin
Generic name:	flibanserin

Ethics review

Approved WMO

Date:	04-02-2010

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	03-03-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
EudraCT	EUCTR2009-016202-16-NL
CCMO	NL30623.042.09