A Phase II Study to Evaluate: Delay in Intravaginal Ejaculatory Latency Time (IELT), Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Two Oral Doses of GSK557296 in a Randomized, Double Blind, Placebo-Controlled, Parallel Group Study in Men with Premature Ejaculation

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To determine if an on demand dosing of 50 or 150 mg of GSK557296 demonstratessuperior efficacy with respect to duration of IELT during an 8 week study periodcompared to placebo in men with premature ejaculation.To assess safety and tolerability of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON35560

Source
ToetsingOnline

Brief title
A Phase II study with GSK557296 in men with premature ejaculation.

Condition

- Reproductive tract disorders NEC

Synonym
premature ejaculation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: GSK557296, pharmacodynamics, pharmacokinetics, premature ejaculation

Outcome measures

Primary outcome

To determine if an on demand dosing of 50 or 150 mg of GSK557296 demonstrates superior efficacy with respect to duration of IELT during an 8 week study period compared to placebo in men with premature ejaculation.

Secondary outcome

To assess safety and tolerability of 50 mg and 150 mg of GSK557296.

To assess change in the Index of Premature Ejaculation (IPE) from baseline and at the end of the 8 weeks of treatment

To characterize the pharmacokinetics of GSK557296 in men with premature ejaculation.

To characterize the dose/exposure response relationship using PK/PD modeling, as data permit.

Study description

Background summary

There are no clear definitions of premature ejaculation. A premature ejaculation can be a psychological, emotional or relational problem. A method or means to delay ejaculation can be very useful.

Current research often uses the "intravaginal ejaculation latency time '(IELTS). This is the time measured from the penetration of the vagina until the beginning of ejaculation.

The cause of premature ejaculation is not yet fully known. In the past it was often thought that premature ejaculation had a psychological cause or had been taught. The last ten years there are increasing indications that premature ejaculation can also be caused by a disturbance of serotonin receptors in the brains. This is possibly congenital. Recent research shows that substances that affect serotonin receptors (antidepressants or SSRIs) are beneficial in extending the IELTS and thus delaying ejaculation. The disadvantage of these drugs is that they must be taken every day and may therefore cause more side effects.

Study objective

To determine if an on demand dosing of 50 or 150 mg of GSK557296 demonstrates superior efficacy with respect to duration of IELT during an 8 week study period compared to placebo in men with premature ejaculation.

To assess safety and tolerability of 50 mg and 150 mg of GSK557296.
To assess change in the Index of Premature Ejaculation (IPE) from baseline and at
the end of the 8 weeks of treatment
To characterize the pharmacokinetics of GSK557296 in men with premature ejaculation.
To characterize the dose/exposure response relationship using PK/PD modeling, as data permit.

Study design

Approximately 75 men will participate in this study. The research is conducted in America, the Netherlands and possibly later in other countries. In the Netherlands there will be approximately 30 healthy male subjects who participate in the trial. The examination includes a medical examination and three visits and one telephone follow-up. Between each visit is a period of 4 weeks. The total study lasts 12 weeks.

Intervention

50 or 150 mg of GSK557296 or placebo during 8 weeks.

Study burden and risks

The risks associated with this investigation are linked together with the possible side effects of the investigational product. The burden on the volunteer will continue to work with the recording periods, venapunctions and the introduction of the cannula. All volunteers are closely monitored and supervised by experienced doctors and studystaff for possible side effects. The following tests will be performed during this trial: physical examination, measuring bloodpressure and hart rate, blood- and urine tests, drugscreen, alcohol tests, ECGs, restrictions in living habits, standardized meals during admission, use of a stopwatch during intercourse, use the electronic diary to complete the subject diary questions and fill out questionnaires.

Al volunteers will be closely monitored by experienced physicians and staff.

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. Males with primary PE, according to the ISSM Consensus Definition.
2. Stable heterosexual relationship.
3. Aged between 18 and 54 years.
4. The subject must make at least four attempts at sexual intercourse on four separate days during the untreated run in period.
5. The average intravaginal ejaculatory latency time must be < 65 seconds based on the study-provided stop watch assessments.

Exclusion criteria

Erectile dysfunction (defined as IIEF-EF domain score < 22).
Active or recent (< 6 months) history of prostatitis.
Presence of penile anatomical abnormalities.
Prior implantation of penile implant for erectile dysfunction.
Primary hypoactive sexual desire.
Spinal cord injury.
History of seizures, within last 6 months.
History of prostate cancer treated or untreated.
History of prostatectomy or prostate procedures for any cause.
Cardiac arrhythmia.
Any condition which would preclude sexual activity.
Labvalues outside normal range.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-12-2009
Enrollment:	30
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	GSK557296
Generic name:	GSK557296

Ethics review

Approved WMO Date:	20-10-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-11-2009
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-02-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-10-2010
Application type:	Amendment

Review commission:	STEG: Stichting Therapeutische Evaluatie Geneesmiddelen (Almere)
Approved WMO Date:	06-10-2010
Application type:	Amendment
Review commission:	STEG: Stichting Therapeutische Evaluatie Geneesmiddelen (Almere)

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	EUCTR2009-011855-40-NL
CCMO	NL29200.040.09