Lybrido Food effect study

Voedsel effect onderzoek naar Lybrido

No registrations found.

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

Summary

ID

NL-OMON25592

Source
Nationaal Trial Register

Brief title
EB96

Health condition

Sexual dysfunction, problems with sexual functioning

Seksuele disfunctie, problemen met het seksueel functioneren

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Pharmacokinetic 90% CI ratio for both AUCinf and Cmax

Secondary outcome

Pharmacokinetic Difference in Tmax and tlag and - Area under the concentration time curve (AUC) - Peak exposure (Cmax) - Time to peak exposure (Tmax) - Lag time (tlag) - Terminal elimination half-life (t½) Residual testosterone per tablet and rupture test analysis after: A. 30 sec sublingual administration B. 60 sec sublingual administration C. 90 sec sublingual administration D. 120 sec sublingual administration Safety E. Nature, frequency and severity of adverse events F. Vital signs and 12-lead ECG G. Safety laboratory tests (urinalysis, hematology, biochemistry)

Study description

Background summary

A total of 18 subjects receive the investigational drug. During the 2 experimental days (where bloodsampling for PK analysis will take place), subjects receive Lybrido under Fed and Fasted conditions in random order. Subjects visit the site à total of 4 times: 1 screening visit, 1 experimental days for two times in a crossover (consisting of an admission,day 1 and day 2) and 1 final follow up visit.

Study objective

Primary objective

1. To determine the effect of food on the pharmacokinetics of sildenafil administered as the Lybrido formulation

2. To determine whether >90% of the testosterone content is released after maximally 90 seconds after sublingual dosing

Secondary objective

1. To evaluate the safety and tolerability of a single dose of Lybrido under fasted and fed conditions

Study design

A total of 18 subjects receive the investigational drug on two experimental days.

Intervention

Lybrido 2 gifts

Contacts

Public
Companion Diagnostics BV
Louis Armstrongweg 78

J. Gerritsen
Almere 1311 RL
The Netherlands
Scientific
Companion Diagnostics BV
Louis Armstrongweg 78

J. Gerritsen
Almere 1311 RL
The Netherlands

Eligibility criteria

Inclusion criteria

1. Evidence of a personally signed and dated informed consent document indicating that the subject (or a legal representative) has been informed of all pertinent aspects of the study

2. Subjects who are willing and able to comply with scheduled visits, treatment plan, laboratory tests and other study procedures

3. Females between 18 and 55 years of age (both inclusive)

4. Healthy based on medical history, physical examination, electrocardiogram, laboratory values and vital signs

5. Body mass index (BMI) ≥18 kg/m2 and ≤ 30 kg/m2

6. Venous access sufficient to allow blood sampling as per protocol

Exclusion criteria

Cardiovascular conditions

1. History of myocardial infarction, stroke, transient ischemic attack, or life-threatening

arrhythmia within the prior 6 months

2. Uncontrolled atrial fibrillation/flutter at screening or other significant abnormality as observed on electrocardiogram (ECG)

3. Systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg.

4. Systolic blood pressure < 90 mmHg and/or diastolic blood pressure< 50 mmHg

Gynecological and obstetric conditions

5. Use of oral contraceptives containing anti-androgens (e.g. crypteron acetate) or anti (androgenic) progestogens (drosperidone, dienogest, chlormadinone acetate and norgestrel)

6. Use of any hormone replacement therapy (HRT) containing more than 50 µg/day of estrogen

7. Pregnancy (note: an urine pregnancy test will be performed in all women prior to the administration of study medication)

8. Lactating or delivery in the previous 6 months

9. Perimenopausal status (cycle shortening/irregular menstrual bleeding in the last 12 consecutive months and/or occurrence of vasomotor symptoms (e.g. hot flashes, night contraceptive sweating) in combination with elevated FSH levels (>40 IU/L) for women 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

10. Liver and/or renal insufficiency

11. Current clinically relevant endocrine disease

12. Positive serology for HIV, Hepatitis B (surface antigen), and/or Hepatitis C Psychological and physiological factors

13. Substance abuse disorder Concomitant medication

14. Use of nitrates or nitric oxide donor compounds

15. Subjects who are taking potent CYP3A4 inhibitors or inducers

16. Use of serotonergic drugs (e.g. Trazodon, fluvoxamide)

17. Use of testosterone therapy within 6 months before study entry

18. Use of any study medication that interferes with study medication (e.g. monoamine oxidase (MAO) inhibitors, calcium channel blockers)

General

19. Illiteracy, unwillingness or inability to follow study procedures

20. Participation in any other clinical drug study in the previous 3 months

21. Smoking

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2014
Enrollment:	18
Type:	Actual

Ethics review

Positive opinion

Date:	08-07-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41076
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4499
NTR-old	NTR4675
CCMO	NL49313.056.14
OMON	NL-OMON41076

Study results