Lybrido Food effect study

Voedsel effect onderzoek naar Lybrido

Gepubliceerd: 08-07-2014 Laatst bijgewerkt: 15-05-2024

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...

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

Samenvatting

ID

NL-OMON25592

Bron
Nationaal Trial Register

Verkorte titel
EB96

Aandoening

Sexual dysfunction, problems with sexual functioning

Seksuele disfunctie, problemen met het seksueel functioneren

Ondersteuning

Primaire sponsor: EB FSD
Overige ondersteuning: EB FSD

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Pharmacokinetic 90% CI ratio for both AUCinf and Cmax

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Lybrido 2 gifts

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	23-06-2014
Aantal proefpersonen:	18
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-07-2014

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41076
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten