

# Lybrido Food effect study

## Voedsel effect onderzoek naar Lybrido

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	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 ( $t_{1/2}$ ) 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 a 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)  $\geq 18$  kg/m<sup>2</sup> and  $\leq 30$  kg/m<sup>2</sup>
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  $\geq 140$  mmHg and/or diastolic blood pressure  $\geq 90$  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. cyproteron acetate) or anti (androgenic) progestogens (drospirenone, dienogest, chlormadinone acetate and norgestrel)

6. Use of any hormone replacement therapy (HRT) containing more than 50  $\mu\text{g/day}$  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