Lybridos Food effect study
Voedsel effect onderzoek naar Lybridos

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22366

Source
Nationaal Trial Register

Health condition

Seksueel functioneren, Seksuele disfunctie

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

90% CI ratio for both AUC0-inf 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)

Safety

A. Nature, frequency and severity of AEs

B. Vital signs and 12-lead ECG

C. Safety laboratory tests (urinalysis, haematology, 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 Lybridos under Fed and Fasted conditions in random order. Subjects visit the site à total of 8 times: 1 screening visit, 1 experimental day 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 buspirone administered as the Lybridos formulation

Secondary objective

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

Study design

A total of 18 subjects receive the investigational drug. During the 2 experimental days (where bloodsampling for PK analysis will take place), subjects receive Lybridos under Fed and Fasted conditions in random order. Subjects visit the site à total of 8 times: 1 screening visit, 1 experimental day for two times in a crossover (consisting of an admission,day 1 and day 2) and 1 final follow up visit.

Intervention

Lybridos 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. Provision of informed consent

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

3. Healthy based on medical history, physical examination (including vital signs), electrocardiogram, laboratory values

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

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

Exclusion criteria

Cardiovascular conditions

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

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

Gynaecological and obstetric conditions

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

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

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

6. Lactating or delivery in the previous 6 months

7. 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)

General

8. Use of any drugs from two weeks prior to admission to the research unit until the follow-up visit, except for allowed oral contraceptives and pain relief (e.g. paracetamol up to 1.5 g per day)

9. Known or suspected hypersensitivity to any of the components of the formulation

10. Liver function tests (i.e., alanine aminotransferase (ALT), aspartate aminotransferase (AST) and bilirubin) significantly above the upper limit of normal (ULN) at repeated measures

11. Any clinically significant history or any other disease or disorder- gastrointestinal,

cardiovascular, respiratory, renal, hepatic, neurological, dermatological, psychiatric, or metabolic as judged by the medical investigator

12. Smoking

13. Unwilling or unable to refrain from consuming grapefruit juice, star fruit and St. Johns Wort 24 hours before and after intake of medication

14. Current regular use of any illicit drugs or history of excessive drinking within 3 months prior to admission to the research unit and/or unwilling or unable to refrain from products containing alcohol from 24 hours before admission and during the stay in the research unit

15. Donation of blood within 3 months prior to admission to the research unit

16. Positive serology test for hepatitis B serum antigen (HBsAg), anti-hepatitis A virus (HAV) (IgM), anti-hepatitis C virus (HCV) or anti human immunodeficiency virus (HIV) 1+2

17. Subjects who, in the opinion of the investigator, are not likely to complete the trial for any reason

18. Participation in any clinical study within 1 month prior to the expected date of enrolment into the study.

19. Employees of the sponsor or CRO involved in the study

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:	Pending
Start date (anticipated):	26-01-2015
Enrollment:	18

Type:	Anticipated

Ethics review

Positive opinion
Date: 23-10-2014

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41098
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4717
NTR-old	NTR4862
CCMO	NL50357.056.14
OMON	NL-OMON41098

Study results