A single dose, open-label, randomised, cross-over bioequivalence study in healthy young men comparing two formulations of escitalopram: the conventional immediate release tablet and the to be marketed orally dispersible tablet

Published: 30-11-2009
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Investigating the bioequivalence of the new formulation of escitalopram.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Mood disorders and disturbances NEC
Study type	Interventional

Summary

ID

NL-OMON32586

Source
ToetsingOnline

Brief title
Bioequivalence study for escitalopram comparing orally dispersible tablets

Condition

- Mood disorders and disturbances NEC

Synonym
depression, depressive disorder

Research involving

Human

Sponsors and support

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

Intervention

Keyword: bio-equivalence, escitalopram, orally dispersible tablet

Outcome measures

Primary outcome

AUC, Cmax

Secondary outcome

Safety, tolerance, perception of user-friendliness.

Study description

Background summary

Escitalopram is used for the treatment of depression and anxiety disorders. In this study an orally dispersible tablet is being investigated, which is more user-friendly and can also be used by patients with dysphagia (35%).

Study objective

Investigating the bioequivalence of the new formulation of escitalopram.

Study design

Single-dose, open-label, randomised, cross-over trial in healthy volunteers.

Intervention

Single dose of escitalopram per study period.

Study burden and risks

The study consists of three study periods, in which the subject will stay in

the research centre for two nights and two days per study period, followed by six return visits for extra blood samples. During the period, blood will be drawn repeatedly. Expected side-effects are mild.

Contacts

Public
Lundbeck

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Copenhagen
Denemarken
Scientific
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2500 Valby
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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. The subject is able to read and understand the Subject Information Sheet.
2. The subject and the physician have signed a study-specific Informed Consent Form. No study-related procedures, including any screening procedures, may be performed before the physician has obtained written informed consent from the subject.
3. The subject is a man.
4. The subject is >=18 years of age and <=55 years of age.
5. The subject has a BMI >=19 kg/m2 and <=29 kg/m2.

6. The subject has a resting pulse and heart rate (as read on the ECG) >=51 bpm and <=100 bpm. For subjects in good physical condition, the lower limit is >=45 bpm.
7. The subject has a resting systolic blood pressure >=91 mmHg and <=140 mmHg and a resting diastolic blood pressure >=51 mmHg and <=90 mmHg. At the Screening Visit or at the Baseline Visit if not assessed at the Screening Visit, an out-of-range resting systolic blood pressure may be repeated once if a medically valid reason is present, for example, white coat hypertension or coming from low outdoor temperatures. The medically valid reason should be documented and signed by the investigator.
8. The subject has an orthostatic blood pressure change <20 mmHg (based on the difference between supine and standing systolic blood pressure).
9. The subject has clinical laboratory test values within the reference ranges. Borderline values may be accepted if they are, in the opinion of the investigator, clinically insignificant.
10. The subject is, in the opinion of the investigator, generally healthy based on assessment of medical history, physical examination, vital signs, electrocardiogram (ECG), and the results of the haematology, clinical chemistry, urinalysis, serology, and other laboratory tests.

Exclusion criteria

1. The subject has taken disallowed medication within 1 week prior to the first dose of IMP (or within 5 half-lives prior to inclusion for any medication ingested, whichever is longer). Disallowed medication is any prescribed medication or over-the-counter (OTC) medication as well as any herbal medicine known to interfere with the metabolic CYP pathways, such as St. John*s Wort. Subjects who have taken any non-prescribed systemic or topical medication may still be entered into the study if, in the opinion of the investigator, the medication will not interfere with the study procedures, study results, or compromise safety.
2. The subject has a significant history of drug or alcohol abuse, defined as an alcohol intake greater than 21 units per week for men, or a history of drug abuse within the last 6 months, or a history of substance abuse deemed significant by the investigator. A unit of alcohol is defined as 250 mL of lager/beer, 100 mL of wine, or 25 mL of spirits.
3. The subject has taken any investigational products within 3 months prior to the first dose of IMP.
4. The subject has previously been dosed with IMP in this study (excluding subjects who have been asked to participate in a crossover cohort of the study).
5. The subject has known hypersensitivity to any of the IMPs or their excipients.
6. The subject has a history of severe drug allergy or hypersensitivity.
7. The subject has a history of or presence of any clinically significant immunological, cardiovascular, respiratory, metabolic, renal, hepatic, gastrointestinal, endocrinological, haematological, dermatological, venereal, neurological, or psychiatric disease or other major disorder.
8. The subject has a history of cancer, other than basal cell or Stage 1 squamous cell carcinoma of the skin, which has not been in remission for at least 5 years prior to the first dose of IMP.
9. The subject has a history of abdominal surgery (excluding laparoscopic cholecystectomy or uncomplicated appendectomy) or thoracic or nonperipheral vascular surgery within 6 months prior to the first dose of IMP.

10. The subject has any concurrent illness that may affect the particular target or metabolism of the IMP.
11. The subject has had a clinically significant illness within 4 weeks prior to the first dose of IMP.
12. The subject has had surgery or trauma with significant blood loss (>500mL) within the last 3 months prior to the first dose of IMP.
13. The subject has donated blood within 3 months prior to the first dose of IMP.
14. The subject has tested positive for human immunodeficiency virus (HIV), hepatitis B surface antigen (HBsAg), or hepatitis C virus antibody (anti-HCV).
15. The subject is a regular smoker or regularly uses other nicotine containing products (for example, snuff, nicotine patch, nicotine chewing gum, mock cigarettes, inhalers). Ex-smokers should have ceased smoking at least 1 months prior to the first dose of IMP.
16. The subject has tested positive after the Screening Visit or at the Safety Baseline Visit for drugs of abuse (opiates, methadone, cocaine, amphetamines (including ecstasy), barbiturates, benzodiazepines and cannabinoids).
17. The subject*s QTc (Bazett*s or Fridericia*s correction) is >450 ms (at the Screening Visit or at the Safety Baseline Visit) as read on the printout of the ECG produced by the ECG equipment and evaluated by the investigator. At the Screening Visit or at the Baseline Visit if not assessed at the Screening Visit, an out-of-range or abnormal ECG may be repeated. In total, 3 ECGs should be recorded consecutively and the investigator should evaluate the triplicate ECG. If the subject*s QTc is >450 ms on at least 2 ECGs, the subject should be excluded.
18. The subject exercises extensively in his/her normal life, like marathon running, triathlon, physical sports at a competitive level.
19. The subject is, in the opinion of the investigator, unlikely to comply with the clinical study protocol or is unsuitable for any other reason.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-01-2010
Enrollment:	30

Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Cipralex
Generic name:	escitalopram
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	30-11-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	23-12-2009
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	EUCTR2009-015108-24-NL
CCMO	NL30634.058.09