Interventional, open-label study investigating the absorption, metabolism and excretion (AME) of the research medication following a single oral dose of the 14C-labeled research medication to healthy men

Published: 04-03-2014
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-to investigate the mass balance following a single oral dose of 14C-labeled research medication-to investigate the pharmacokinetics of total radioactivity in plasma and whole blood-to investigate and quantitate metabolites of the research...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON40688

Source
ToetsingOnline

Brief title
15867A (CS0209)

Condition

- Schizophrenia and other psychotic disorders

Synonym
mental disorder

Research involving

Human

Sponsors and support

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

Intervention

Keyword: healthy men, mass balance, open label

Outcome measures

Primary outcome

AME endpoints

Secondary outcome

Safety

Study description

Background summary

The research medication is a new medication under development for the treatment of diseases related to the central nervous system (CNS).

Study objective

-to investigate the mass balance following a single oral dose of 14C-labeled research medication
-to investigate the pharmacokinetics of total radioactivity in plasma and whole blood
-to investigate and quantitate metabolites of the research medication (reported separately)
-to investigate the pharmacokinetics of the research medication and the metabolite
-to investigate the safety and tolerability of a single dose of the research medication in healthy men

Study design

This is an interventional, open-label study investigating the absorption,

metabolism and excretion (AME) of the research medication following a single oral dose of the 14C-labeled research medication to healthy men

Intervention

The study will start with a screening. At the screening a physical examination will take place and a few other standard medical assessments will be performed (ECG, vital signs). Furthermore a blood and urine sample will be taken for laboratory tests and an alcohol breath test and drug screen will be done.

During the stay in the clinic the subject will receive 14C-labeled research medication once on Day 1. On several time points blood will be taken and feces and urine will be collected. The subjects will be asked for possible side effects on regular basis. Furthermore several safety assessments will be done frequently.

On ambulant visits a blood, urine and feces sample will be taken.

Finally, a follow-up visit will take place.

Study burden and risks

Two clinical studies with the research medication have been conducted, one study in healthy volunteers and one in patients with schizophrenia. No serious adverse events were reported in both studies.

In the study with healthy volunteers all AEs were of mild intensity and short duration. The AE's in patients with schizophrenia were of mild to moderate intensity, with the exception of one event of severe somnolence which resolved after a few hours.

Some adverse events were reported, possibly linked to the use of the study drug. These adverse events include dizziness, tiredness, headache, orthostatic dizziness, non-sustained supra-ventricular tachycardia, sleepiness, poor sleep, orthostatic hypotension, insomnia, muscle pain, defecation frequency decreased, feeling of swollen tongue, light headedness, ALAT increase above 3 times of the upper limit of the reference range (liver value), abdominal cramps, abdominal pain, low blood pressure, increased creatine kinase (important enzyme for the heart and other important organs), and vomiting.

The radioactive substance that is used for this study is broken down rapidly.

The blood collection may cause discomfort or bruising. Occasionally, fainting, an infection at the blood sampling site, bleeding and blood clot formation can occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male

Exclusion criteria

Clinical significant abnormalities at medical research

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):	27-03-2014
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[14C] -Lu AF35700
Generic name:	[14C] -Lu AF35700
Product type:	Medicine
Brand name:	Lu AF35700
Generic name:	Lu AF35700

Ethics review

Approved WMO Date:	04-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-04-2014

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-04-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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	EUCTR2013-004049-17-NL
CCMO	NL48037.056.14