Single-Center, Open-label Study Investigating the Excretion Balance, Pharmacokinetics and Metabolism of a Single Oral Dose of [14C]-radio-labeled RO4602522 in Healthy Male Volunteers

Published: 03-05-2012
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Primary:* To explore the routes and rates of elimination of [14C]-labeled RO4602522.* To investigate the pharmacokinetics of total drug related material, RO4602522 and its metabolites as appropriate.Secondary:* To investigate metabolic profiles of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36882

Source
ToetsingOnline

Brief title
[14C]-RO4602522 ADME study

Condition

- Neurological disorders NEC

Synonym
Alzheimer's disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: Hoffmann-La Roche
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: [14C]-RO4602522, ADME

Outcome measures

Primary outcome

Pharmacokinetics:

Bloodsamples for the analysis of RO4602522 and amount of radioactivity will be collected during the clinic period.

Urine and feces for the analysis of RO4602522 and amount of radioactivity will be collected during the clinic period and, if required, after leaving the clinic until at maximum 20 days after dosing.

Secondary outcome

Blood, urine, and feces samples for the analysis of the metabolic profile of RO4602522 will be collected during the clinic period.

Study description

Background summary

RO4602522 is a new investigational compound that may eventually be used for the treatment of Alzheimer*s disease. RO4602522 is an inhibitor of MAO-B. MAO-B has been chosen as a target for drug development in Alzheimer*s disease because there is evidence to suggest that it is involved in the etiology of the disease. In patients with Alzeimer*s disease, brain MAO-B activity is increased compared with age-matched controls.
RO4602522 is not registered as a drug but has been given to humans before.

Study objective

Primary:
* To explore the routes and rates of elimination of [14C]-labeled RO4602522.
* To investigate the pharmacokinetics of total drug related material, RO4602522 and its metabolites as appropriate.
Secondary:
* To investigate metabolic profiles of RO4602522 in plasma and excreta and characterize any major metabolites.

Study design

This is an open-label study, with 6 healthy male volunteers. The volunteers will receive [14C]-labeled RO4602522 as a capsule for oral administration.

Intervention

A single dose of 60 mg radio labeled study medication in the form of an oral capsule.
In this study radio labeled RO4602522 will be used. The amount of radioactivity in this dose will be 2.81 MBq (MBq = megaBecquerel, this is a unit to express the amount of radioactivity in the study drug). The average environmental background radiation burden in The Netherlands is approximately 2 mSv per year (mSv = miliSievert, this is the unit which indicates the burden on the human body; thus the effect on the human body of the amount of radioactivity administered). The additional radiation burden in this study due to the administration of 2.81 MBq 14C-labeled RO4602522 is calculated to be 0.5 mSv. This is approximately 25 % of the average annual radiation burden.

Study burden and risks

During the study, several assessments are performed that can be more or less inconvenient:

Blood draw, indwelling canula
During this study less then 500 ml of blood will be drawn. It is anticipated that on Day -1 an indwelling canula will be inserted for most of the blood sampling on Day 1 and 2. On the other days during this study, blood will be drawn by direct puncture of the vein.

Collection of urine and feces
Urine and feces will be collected until the day of discharge (thus until Day 8 - 12). In addition, when the radioactivity level is above the pre-defined levels, collection of urine and feces may have to be continued at home.

Heart trace (ECG*s)
ECG*s will be made on Day 1 and day of discharge.

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 subjects
35-55 yrs, inclusive
BMI: 18.0-30.0 kg/m2, inclusive
non-smoking

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 90 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study

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):	08-05-2012
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	03-05-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-05-2012
Application type:	First submission
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	EUCTR2012-000587-26-NL
CCMO	NL40577.056.12