A Single-Center, Open-Label, Parallel Study to Investigate the Effects of Multiple Doses of Ketoconazole on the Pharmacokinetics of a Single Oral Dose of RO4602522 in Healthy Male Subjects.

Published: 05-06-2012
Last updated: 26-04-2024

The purpose of the study is to find out if there is a possible influence of Ketoconazole on the effect of RO4602522 (this is called pharmacodynamics). it will be investigated whether and if so to what extent Ketoconazole influences how fast...

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

Summary

ID

NL-OMON36948

Source
ToetsingOnline

Brief title
RO4602522 / Ketoconazole DDI study

Condition

- Neurological disorders NEC

Synonym
Alzheimer's disease, dementia

Research involving
Human

Sponsors and support

Primary sponsor: F. Hoffmann-La Roche Ltd
Source(s) of monetary or material Support: Pharmaceutische industrie.

Intervention

Keyword: DDI, Ketoconazole, RO4602522

Outcome measures

Primary outcome

Pharmacokinetics:

Bloodsamples for the analysis of RO4602522 and metabolitesy will be collected

during the clinic period.

Urine for the analysis of RO4602522 will be collected during the clinic period

at he clinic until 48 hours after dosing.

Secondary outcome

NA

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

The purpose of the study is to find out if there is a possible influence of Ketoconazole on the effect of RO4602522 (this is called pharmacodynamics). it will be investigated whether and if so to what extent Ketoconazole influences how fast RO4602522 is absorbed and eliminated from the body (this is called pharmacokinetics).
In addition it will be investigated wheter RO4602522 administrated with Ketoconazole is safe and well tolerated.

Study design

This is an non-randomized parallel, open-label study, with 34 healthy male volunteers. The volunteers will receive RO4602522 and/or ketoconazole as a tablet for oral administration.

Intervention

Group 1 will receive a single dose of 15 mg study medication RO4602522 in the form of an oral tablet on Day 1.

Group 2 will receive a twice daily dose of 200 mg Ketoconazole in the form of an oral tablet from Day 1 until Day 17. Also on Day 4 this group will receive a single dose of 15 mg study medication RO4602522 in the form of an oral tablet in combination with Ketoconazole.

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possible an infection after blood draw i.e. indwelling canula.

Contacts

Public
F. Hoffmann-La Roche Ltd

Grenzacherstrasse 124,
4070 Basel
CH
Scientific
F. Hoffmann-La Roche Ltd

Grenzacherstrasse 124,
4070 Basel
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy male subjects
18-45 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
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-06-2012
Enrollment:	34
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Nizoral
Generic name:	Ketoconazole
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	05-06-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-06-2012
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	EUCTR2012-001195-11-NL
CCMO	NL40681.056.12