A phase I, open-label study to investigate the absorption, metabolism, excretion, and mass balance of [14C]QLT091001 following single oral dose in healthy male subjects

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The study objectives are:- to characterize the biotransformation pathways, the routes and rates of excretion, and total recovery of the 14C-labeled research medication and its radiolabeled metabolites- to characterize the pharmacokinetics (PK) of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ocular structural change, deposit and degeneration NEC
Study type	Interventional

Summary

ID

NL-OMON35776

Source
ToetsingOnline

Brief title
RET HV 03

Condition

- Ocular structural change, deposit and degeneration NEC

Synonym
inherited retinal diseases

Research involving
Human

Sponsors and support

Primary sponsor: QLT Inc.
Source(s) of monetary or material Support: QLT Inc.

Intervention

Keyword: healthy male subjects, mass balance, pharmacokinetics, phase 1

Outcome measures

Primary outcome

To characterize the biotransformation pathways, the routes and rates of excretion, and total recovery of the 14C-labeled research medication and its radiolabeled metabolites.

Secondary outcome

To characterize the pharmacokinetics (PK) of the research medication and its major metabolites.

To document the safety and tolerability.

Study description

Background summary

The research medication is a new medication developed for the treatment of inheretid retinal diseases (IRD).

Study objective

The study objectives are:
- to characterize the biotransformation pathways, the routes and rates of excretion, and total recovery of the 14C-labeled research medication and its radiolabeled metabolites
- to characterize the pharmacokinetics (PK) of the research medication and its major metabolites
- to document the safety and tolerability

Study design

A phase I, open-label study to investigate the absorption, metabolism, excretion, and mass balance of the research medication following a single oral dose in healthy male subjects.

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 the 14C-labeled research medication once on Day 1. On several time points blood will be taken and all urine and feaces will be collected. The subjects will be asked for possible side effects on regular basis. Furthermore several safety assessments (ECG, vital signs) will be done frequently and an ophthalmic examination will be performed three times. On Day 10 the subjects will be discharged from the clinic after they have met met the discharge criteria regarding radioactivity levels in samples of blood, urine and feces. When these criteria have not been met by the morning on Day 10, they will stay in the clinic until the criteria are met.

It appeared that the amount of radioactivity was decreased sufficiently for the subjects to leave the clinic, however, it was not yet totally excreted by the body. To have a complete insight of the excretion of the research medication QLT091001, the sponsor would like to further determine the radioactivity in your samples of blood, urine and feces for maximally 4 times with an interval of 2 weeks.

Study burden and risks

The research medication has been previously tested in humans and animals and was generally well tolerated. A total of 27 humans have received the research medication in a trial. In healthy subjects (20 volunteers), a number of side-effects, related to the research medication have been reported. These side-effects included mild transient headaches and facial flushing and burning sensation, decreased appetite, lack of energy, sensitivity for light, change of certain blood parameters (decreased haemoglobine, red blood cells and triglycerides).
Based on studies with the research medication in animals and human experience with drugs resembling the research medication effects on the liver are possible. These effects are expected to be reversible.

The dose level is selected on the basis of research results in animals and

humans. The risk to health at these dose levels is limited but subjects may experience one of the above mentioned side-effects or other symptoms not previously reported. The health of the subjects will be closely monitored during the trial to minimize these risks.

The radioactive substance that is used for this study is broken down rapidly. The total radiation load in this study is estimated as 1.4 millisievert.

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):	21-04-2011
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[14C]QLT091001
Generic name:	[14C]QLT091001
Product type:	Medicine
Brand name:	QLT091001
Generic name:	QLT091001

Ethics review

Approved WMO

Date:	31-03-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	08-04-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-05-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-08-2011
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-10-2011
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	EUCTR2011-001324-37-NL

Register	ID
CCMO	NL36276.056.11