A randomized double-blind, placebo-controlled, single and multiple ascending dose study to evaluate the safety and pharmacokinetics of OCR 002 in healthy volunteers.

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SADTo evaluate the safety and tolerability of ascending single doses (SAD) of OCR 002 administered as intravenous (IV) infusions in healthy volunteersTo evaluate the plasma pharmacokinetics (PK) of phenylacetate and ornithine and glutamine after a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatic and hepatobiliary disorders
Study type	Interventional

Summary

ID

NL-OMON34455

Source
ToetsingOnline

Brief title
OCR-002 SAD+MAD study in HV

Condition

- Hepatic and hepatobiliary disorders

Synonym
Liver failure

Research involving
Human

Sponsors and support

Primary sponsor: Ocera Therapeutics
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: liver failure, OCR-002

Outcome measures

Primary outcome

Pharmacokinetics: plasma OCR-002 concentrations, pharmacokinetic parameters

Safety : adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination

Secondary outcome

N/A

Study description

Background summary

The drug to be given (OCR-002) is a new, investigational compound that may eventually be used for the treatment of acute liver failure.
Due to liver failure, certain waste products are not removed from the body. One of these is ammonia. The amount of ammonia that remains in the body disturbs the normal function of the brain and may ultimately lead to death. OCR-002 is meant to reduce the amount of ammonia in the body through another mechanism, that not depends on the liver.

Study objective

SAD
To evaluate the safety and tolerability of ascending single doses (SAD) of OCR 002 administered as intravenous (IV) infusions in healthy volunteers
To evaluate the plasma pharmacokinetics (PK) of phenylacetate and ornithine and glutamine after a single IV infusion
To evaluate the urine PK of Phenylacetylglutamine (PAGN) after a single IV infusion

MAD
to evaluate the safety and tolerability of multiple ascending single doses of OCR-002 administered as IV infusions in healthy volunteers
to evaluate the plasma PK of phenylacetate and ornithine and glutamine after multiple IV infusions
To evaluate the urine PK of PAGN after multiple IV infusions

Study design

SAD
a randomized, double-blind, placebo-controlled, single-ascending dose study with two alternating cohorts and 3 cohorts (non-alternating) of six healthy male and/or healthy female subjects each ;
MAD
a randomized, double-blind, placebo-controlled, multiple-ascending dose study with six cohorts of six healthy male and/or healthy female subjects each receiving an iv infusion of OCR-002 or placebo (five verum and one placebo) for five days

Intervention

Active substance OCR-0002 or placebo

Study burden and risks

Procedures: pain, light bleeding, aematoma, possibly an infection
Medication : increased or decreased heart rate, extra heart beats, nausea, decreased appetite and somnolence

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 and female subjects
18 - 55 years of age

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS/ In case of participation in another drug study withing 60 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 to the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-05-2010
Enrollment:	66
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	-
Generic name:	-

Ethics review

Approved WMO Date:	18-05-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-05-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-07-2010
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-07-2010
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	EUCTR2010-020111-37-NL
CCMO	NL32414.056.10