A study evaluating the pharmacokinetics, safety and tolerability of OP2113 administered intravenously in healthy volunteers and a marketed formulation administered orally

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Primary objectives1. To evaluate the pharmacokinetic (PK) profile of the parent compound (anethole trithione, ATT) and its main metabolite (5-[4-hydroxyphenyl]-3H-1,2-dithiole-3-thione, ATX) following administration of a range of doses of i.v....

Ethical review	Approved WMO
Status	Completed
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON48072

Source
ToetsingOnline

Brief title
OP2-CS-001 OP2 Drugs

Condition

- Myocardial disorders

Synonym
inhibition of ROS production, reduction/prevention of myocardial necrosis

Research involving
Human

Sponsors and support

Primary sponsor: OP2 Drugs
Source(s) of monetary or material Support: OP2 Drugs

Intervention

Keyword: OP2113, PK, safety, tolerability

Outcome measures

Primary outcome

Pharmacokinetic endpoints of ATT (free) and ATX (free and total) include Cmax, Tmax, AUC0-last, AUC0-inf, AUC0-24,), t1/2, *Z, AR (only for PK samples collected during TID oral dosing). Pharmacokinetic endpoints of ATT (free) only are: CL/F (oral formulation) or CL (i.v. formulation), Vz/F (oral formulation) or Vz (i.v. formulation, C0 (i.v. formulation).

Secondary outcome

Safety parameters include adverse events (AEs), vital signs, electrocardiogram (ECG), clinical laboratory assessments and local tolerability (only for i.v. dosing).

Study description

Background summary

OP2 Drugs SAS is investigating whether OP2113 can limit the damage to the heart tissue that is caused following a standard intervention after an acute heart attack. OP2113 will be administered directly into the blood and this study evaluates OP2113 administered as an injection and infusion for the first time.

Study objective

Primary objectives
1. To evaluate the pharmacokinetic (PK) profile of the parent compound

(anethole trithione, ATT) and its main metabolite (5-[4-hydroxyphenyl]-3H-1,2-dithiole-3-thione, ATX) following administration of a range of doses of i.v. OP2113.
2. To evaluate the PK profile of ATT and ATX following administration of an oral formulation containing ATT (after a single dose and after multiple doses).

Secondary objective
1. To evaluate the safety and tolerability, including local tolerability, of a range of doses of i.v. OP2113.
2. To evaluate the safety and tolerability of an oral formulation containing ATT (single dose and multiple doses).

Study design

Single site, randomized, placebo-controlled, open-label (for Oral Dosing Period) and single-blind (for i.v administration Periods), ascending dose, cross-over study.

Intervention

Sulfarlem S25 tablets of 25 mg
intravenous bolus injection and 12-hour infusion of OP2113
intravenous bolus injection and 12-hour infusion of saline placebo

Study burden and risks

Since this study is being executed in healthy volunteers, there are no anticipated benefits of the IMP. Please see the IMPD for further information.

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 aged between 18 and 65 years (inclusive) with a body mass index (BMI) of *18.0 kg/m2 and * 30.0 kg/m2 (inclusive) at Screening.
Further inclusion criteria can be found in the protocol section 8.4.1

Exclusion criteria

Relevant prior or ongoing medical condition that, in the Investigator*s opinion, could adversely affect the safety of the subject.
History of clinically-significant hypersensitivity to any of the study drugs, excipients or materials used to administer the study medication.
Further exclusion criteria can be found in the protocol section 8.4.2

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-04-2019
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	03-04-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-04-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-08-2019
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	EUCTR2019-000933-37-NL
CCMO	NL69491.056.19

Study results

Date completed: 15-08-2019

Results posted: 19-01-2022

First publication
27-08-2021