A single-center, randomized, double-blind, two-period cross-over study to investigate the effect of a single intravenous dose of rifampicin on the pharmacokinetics of ACT-246475 in healthy subjects.

Published: 18-12-2018
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Myocardial disorders
Study type	Interventional

Summary

ID

NL-OMON46064

Source
ToetsingOnline

Brief title
CS0310 (ID-076-106)

Condition

- Myocardial disorders

Synonym
Acute myocardial infarction; heart attack

Research involving

Human

Sponsors and support

Primary sponsor: Idorsia Pharmaceuticals Ltd
Source(s) of monetary or material Support: Idorsia Pharmaceuticals Ltd.

Intervention

Keyword: Pharmacokinetics, Safety, Tolerability

Outcome measures

Primary outcome

The pharmacokinetic parameters

Secondary outcome

The safety endpoint parameters are frequency and severity of adverse events,

vital signs, electrocardiography (ECG), safety laboratory tests and urinalysis.

Study description

Background summary

When somebody has a heart attack, it is important that this person is treated as soon as possible so the heart gets damaged as little as possible. ACT-246475 is a compound that is being developed to be used as an emergency treatment for a heart attack.

Study objective

The purpose of the study is to determine how a single administration of rifampicin influences the uptake and breakdown of ACT-246475. Furthermore, the safety and tolerability of ACT-246475 when administered after administration of rifampicin, will be investigated.

Primary objective
To evaluate the effect of a single intravenous (i.v.) dose of rifampicin on the PK of ACT-246475 in healthy subjects.

Secondary objective

To evaluate the safety and tolerability of ACT-246475 when administered following i.v. infusion of saline or rifampicin in healthy subjects.

Study design

A single-center, randomized, double-blind, two-period, cross-over study to investigate the effect of a single intravenous dose of rifampicin on the pharmacokinetics of ACT-246475 in healthy subjects.

Intervention

ACT-246475 + saline or
ACT-246475 + rifampicin

Study burden and risks

The risk to health at the chosen dose is limited, but the volunteers may experience any of the side effects written in the ICF or symptoms that have not been reported before.

Volunteers health is closely monitored during the study to minimize these risks.

If the volunteers experience side effects, the investigator will treat them where necessary. If new information is available on the safety of the study medication, the volunteers are informed as soon as possible. The blood collection procedure is not dangerous.

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 to 30.0 kg/m2 (inclusive) at Screening.;Further inclusion criteria can be found in the protocol section 3.2.2

Exclusion criteria

1. Previous exposure to ACT-246475.
2. Previous exposure to rifampicin within 3 months prior to Screening.
3. Known hypersensitivity to P2Y12 receptor antagonists or rifampicin or to any of the rifamycins, or any of their excipients. ;Further exclusion criteria can be found in the protocol section 3.2.3.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-01-2019
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ACT-246475
Generic name:	N.a.
Product type:	Medicine
Brand name:	Rifadin
Generic name:	Rifampicin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-12-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-12-2018
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	EUCTR2018-004226-28-NL
CCMO	NL68150.056.18