A single-center, randomized, double-blind, two-period cross-over study to investigate the effect of rifampicin on the pharmacokinetics of clazosentan in healthy male subjects.

Published: 15-06-2018
Last updated: 11-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Aneurysms and artery dissections
Study type	Interventional

Summary

ID

NL-OMON45870

Source
ToetsingOnline

Brief title
CS0296 (ID-054-106)

Condition

- Aneurysms and artery dissections

Synonym
cerebral vasospasm (cerebral hemorrhage)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Pharmacokinetic, 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 bleeding occurs in the brain, the brain tissue responds by contracting the blood vessels near the bleeding. This cramping of blood vessels can result in local brain cells receiving not enough blood. The brain areas that receive too little blood may in turn die. Clazosentan is being developed to prevent and/or reverse cramping of blood vessels after a stroke.

Study objective

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

Primary objective
To evaluate the influence of a single intravenous (i.v.) infusion of rifampicin on the PK of clazosentan

Secondary objective
To evaluate the safety and tolerability of clazosentan when administered following i.v. infusion of saline or rifampicin.

Study design

A single-center, randomized, double-blind, two-period cross-over study to investigate the effect of rifampicin on the pharmacokinetics of clazosentan 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 breathtest and drug screen will be done.

During the stay in the clinic the subject will receive the study medication (a single i.v. infusion of saline or rifampicin (600 mg) for 30 min in the morning of Day 1 of Treatment A or Treatment B, respectively, prior to clazosentan 15 mg/h for 3 h.) and on several time points blood will be taken
and urine will be collected. The subjects will be asked for possible side effects on regular basis. Furthermore several
safety assessments will be done frequently.

Finally, a follow-up (end of study) visit will take place and a follow-up phone call will take place .

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 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 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 clazosentan.
2. Previous exposure to rifampicin within 3 months prior to Screening.
3. Known hypersensitivity to clazosentan or rifampicin or treatments of the same class, 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-07-2018
Enrollment:	14
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N.A.
Generic name:	Clazosentan
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	15-06-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-07-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	22-08-2018
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	EUCTR2018-001607-36-NL
CCMO	NL66167.056.18