Single-center, double-blind, randomized, placebo-controlled, single-ascending dose
and food interaction study to investigate the tolerability, safety, pharmacokinetics,
and pharmacodynamics of ACT-389949 in healthy male subjects

Published: 08-11-2011
Last updated: 30-04-2024

• to evaluate the safety and tolerability of ascending single oral doses of the test compound ACT-389949 (test medication) in healthy male subjects• to study how the test compound ACT-389949 is absorbed, broken-down and excreted by the body and how…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	White blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON35247

Source
ToetsingOnline

Brief title
ACT-389949

Condition

- White blood cell disorders
- Immune disorders NEC

Synonym
Acute inflammation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: double-blind, placebo-controlled, randomized, single-ascending dose

Outcome measures

Primary outcome

• to evaluate the safety and tolerability of ascending single oral doses of the test compound ACT-389949 (test medication) in healthy male subjects

Secondary outcome

• to study how the test compound ACT-389949 is absorbed, broken-down and excreted by the body and how it affects the functioning of the body

• to investigate whether increasing the dose of ACT-389949 with a certain proportion results in an increase in the effect of ACT-389949 with that same proportion

• to study the impact of food on how a single dose of ACT-389949 is absorbed, broken-down and excreted by the body

Study description

Background summary

Acute inflammation is a protective response of our immune system triggered by activities within the body that signal injury or infection. If signals that are naturally present in our body fail to resolve (put an end to) the inflammation, tissue damage and chronic, life-long inflammatory disease may result. ACT-389949 is a compound that can bind to and activate a protein reported to play a central role in the resolution of inflammation. ACT 389949 may provide a new approach to the treatment of persistent inflammatory diseases

Study objective

• to evaluate the safety and tolerability of ascending single oral doses of the test compound ACT-389949 (test medication) in healthy male subjects

• to study how the test compound ACT-389949 is absorbed, broken-down and excreted by the body and how it affects the functioning of the body

• to investigate whether increasing the dose of ACT-389949 with a certain proportion results in an increase in the effect of ACT-389949 with that same proportion

• to study the impact of food on how a single dose of ACT-389949 is absorbed, broken-down and excreted by the body

Study design

Each dose group contains 8 healthy male subjects of which 6 will receive a single oral dose of ACT-389949 (ranging from 1 to 1000 mg) and 2 will receive placebo. Depending on the dose level, the drug will be administered in 1-10 capsules. Each dose level will be investigated in a new subgroup. Thus, each subject will participate in one treatment period only, with the exception of the subjects in the food interaction part (4th dose group), who will participate in two treatment periods, one with medication given in fasted condition, the other one with medication given after breakfast. The two treatment periods will be separated by 7 to 10 days.

Intervention

n.a.

Study burden and risks

With new drugs such as ACT-389949, no side effects are known yet as ACT-389949 has not been previously tested in humans. The selection of the starting dose is based on the recommendation of the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

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 Caucasian male subject

Exclusion criteria

Clinically significant abnormalities at screening

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):	22-11-2011
Enrollment:	64
Type:	Actual

Ethics review

Approved WMO Date:	08-11-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-11-2011
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	EUCTR2011-004403-21-NL
CCMO	NL38665.056.11