A Phase 1 Study to Compare the Pharmacokinetics of CAL-101 Capsules to Tablets in Healthy Male Subjects.

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Primary: to evaluate the pharmacokinetics of a single 100 mg dose of CAL-101 administered as a capsule (unmicronized formulation), a capsule (micronized formulation) or a tablet in normal healthy male subjectsSecondary: to evaluate the safety of a...

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

Summary

ID

NL-OMON35094

Source
ToetsingOnline

Brief title
CAL-101 BE study.

Condition

- White blood cell disorders

Synonym
Blooddisease, leukemia/lymophoma

Research involving
Human

Sponsors and support

Primary sponsor: Calistoga Pharmaceuticals Inc.
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: CAL-101, Leukemia, Lymophoma, p110 delta

Outcome measures

Primary outcome

Safety , Pharmacokinetics

Secondary outcome

N/A

Study description

Background summary

The drug CAL-101 to be given is a new, investigational compound that may eventually be used for the treatment of leukemia and lymphoma.
Leukemia and lymophoma are both diseases of the blood, in particular the white blood cell. In leukemia typically there is an excessive increase of immature white blood cells. Normally a white blood cell matures and after a certain period it dies and is replaced by a new white blood cell. In lymphoma, the white cells begin to multiply uncontrollably, producing cancerous cells that have the abnormal capacity to invade other tissues throughout the body. It has been found that with leukemia and lymphoma white blood cells survive longer, because among other things they have an increased activity for an enzyme called p110 delta. If this enzyme, p110 delta, is inhibited by CAL-101, the leukemia and lymphoma cells may die off. In animals given high doses of CAL-101, effects were seen mainly on cells of the bone marrow and the liver. In an ongoing study of patients with leukemia and lymphoma a number of signs have been seen for the possible treatment of these illnesses.

Study objective

Primary: to evaluate the pharmacokinetics of a single 100 mg dose of CAL-101 administered as a capsule (unmicronized formulation), a capsule (micronized formulation) or a tablet in normal healthy male subjects
Secondary: to evaluate the safety of a single 100 mg dose of CAL-101 in healthy male subjects

Study design

Design: a randomized, three-period crossover study.

Procedures and assessments
Screening and follow-up: clinical laboratory, vital signs, physical examination, ECG; at eligibility screening: medical history, height, weight, drug screen, HBsAg, anti HCV, anti-HIV 1/2; follow-up at discharge on Day 12; drug screen, vital signs, ECG, haematology and clinical chemistry to be repeated upon admission
Observation period: one period in clinic from -17 h before drug administration on Day 1 up to 72 h after drug administration on Day 9
Blood sampling: for pharmacokinetics of CAL-101 in plasma: pre-dose and 15, 30 min, 1, 1.5, 2, 3, 4, 6, 8, 12, 24, 36 and 48 h post-dose on Days 1, 5 and 9
Safety assessments: adverse events: throughout the study; vital signs: once on Days 1-11
Bioanalysis: analysis of plasma CAL-101 samples using a validated method by PRA

Intervention

Active substance: CAL-101

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

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 volunteers
- age between 18 and 65 years (inclusive)
- BMI between 18 and 30 kg/m2
- non heavy or average smoker
- at screening the state of health satisfies the entry requirements

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor (500 mL or more) 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 the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-03-2010
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	15-02-2010
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-02-2010
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	EUCTR2010-018378-19-NL
CCMO	NL31502.056.10