A phase 1, open-label study to investigate the absorption, metabolism, excretion, and mass balance of [14C]pacritinib following a single oral dose in healthy male subjects.

Published: 16-06-2014
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To characterize the clearance pathways, the routes of excretion, total recovery of radioactivity, pacritinib and its major metabolites in healthy subjects following administration of a single oral dose of 400 mg [14C]pacritinibTo characterize the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON41159

Source
ToetsingOnline

Brief title
PAC102 (CS0218)

Condition

- Other condition

Synonym
abnormal growth of blood cells in the bone marrow, Myeloproliferative disorders

Health condition

Chronic Myeloproliferative Disorders

Research involving
Human

Sponsors and support

Primary sponsor: CTI BioPharma Corporation
Source(s) of monetary or material Support: Cell Therapeutics;Inc.

Intervention

Keyword: Absorption, Excretion, Mass balance, Metabolism

Outcome measures

Primary outcome

Absorption

Metabolism

Excretion

Mass balance

Secondary outcome

Not applicable

Study description

Background summary

To investigate the absorption, metabolism, excretion as well as safety/tolerability of pacritinib after a single oral dose.

Study objective

To characterize the clearance pathways, the routes of excretion, total recovery of radioactivity, pacritinib and its major metabolites in healthy subjects following administration of a single oral dose of 400 mg [14C]pacritinib

To characterize the pharmacokinetics (PK) of total radioactivity, pacritinib and its major metabolites following administration of a single oral dose of 400 mg [14C]pacritinib in healthy subjects.

To assess the safety and tolerability of a single oral dose of 400 mg [14C]pacritinib in healthy subjects.

Study design

This is a phase 1, open-label study to investigate the absorption, metabolism, excretion, and mass balance of [14C]pacritinib following a single oral dose in healthy male subjects.

Intervention

The study will start with a screening visit. During the screening visit standard medical assessments including safety laboratory tests (blood draw, urine collection), an alcohol breath test, urine drug screen, a physical examination, ECG and a vital signs measurement will be performed. After the subject passes all above mentioned tests,the subject will be enrolled in the study.

During study the subject will enter the clinic. The subjects will receive 1 radiolabeled medication once on day 1. The subject will be asked on a regular basis for possible side effects, blood, urine, fecal samples will be collected for PK and the vital signs, ECG will be checked during the confinement period and possibly required follow-up visits.On a daily basis blood and urine samples will be taken for safety laboratory tests.

Finally a End of Study examination will be performed. During this visit the subjects will be asked for possible side effects, blood and urine will be collected for safety, the vital signs and ECG will be checked and a physical examination will be conducted.

Study burden and risks

The risk is small. The patients will be closely monitored. The patients will be regularly questioned for any side effects and safety tests are scheduled (vital signs). The patients will be asked to report, as soon as possible, any changes in physical and/or mental well being.

The blood collection procedure is not dangerous, but may cause discomfort or bruising. Occasionally, fainting or an infection at the blood sampling site may occur.

Shaving may be required for proper placemant of ECG patches. This may cause irritation or bleeding of the skin. ECG patches may cause redness, itching, rash, or blisters on the skin and/or hair loss due to removal of ECG patches.

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

Non-smoking men between 18 and 55 years of age (inclusive).

Exclusion criteria

Any severe acute or chronic medical condition, psychiatric condition, or laboratory abnormality that in the Investigator's opinion may increase the risk associated with study participation or administration of study treatment, or interfere with the interpretation of study results (such as gastrointestinal surgical history or obstructive uropathy).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2015
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	[14C]-Pacritinib
Generic name:	[14C]-SB1518
Product type:	Medicine
Brand name:	Pacritinib
Generic name:	SB1518

Ethics review

Approved WMO

Date:	16-06-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	14-07-2014
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	EUCTR2014-002065-29-NL
CCMO	NL49591.056.14