A Phase I Study to Investigate the Absorption, Metabolism, and Excretion of Radiolabeled [14C] R924548 Following Single Oral Dose Administration in Healthy Male Subjects

Published: 19-06-2012
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- To assess the absorption, distribution, metabolism and excretion of R924548 after a single oral dose- To assess the safety and tolerability of R924548 after a single oral dose

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

Summary

ID

NL-OMON37118

Source
ToetsingOnline

Brief title
R548 ADME study

Condition

- Autoimmune disorders

Synonym
immune-mediated diseases, rheuma

Research involving
Human

Sponsors and support

Primary sponsor: Rigel Pharmaceuticals, Inc
Source(s) of monetary or material Support: Rigel Pharmaceuticals Inc.;USA

Intervention

Keyword: [14C] R924548, Healthy subjects, Immune-mediated diseases

Outcome measures

Primary outcome

- Plasma PK of R507 and R689

- Total concentration radioactivity in plasma and whole blood over time

- Total amount of radioactivity recovered in urine and feces

- Characterized metabolites of R924548 (R548) in plasma, urine, and feces

Secondary outcome

Safety and tolerability: adverse events, vital signs, ECG-parameters,

laboratory parameters, physical examination

Study description

Background summary

The study drug to be given, R548, is a new investigational drug that may eventually be used for the treatment of immunemediated diseases such as rheumatoid arthritis. R548 is a study drug that will convert in the body into an inhibitor of Janus kinase 1 (JAK1) and Janus kinase 3 (JAK3), which are enzymes that contribute to the development of inflammation in rheumatoid arthritis.
The study medication is not registered as a drug but has been given to humans before.

Study objective

- To assess the absorption, distribution, metabolism and excretion of R924548 after a single oral dose

- To assess the safety and tolerability of R924548 after a single oral dose

Study design

An open label study in 6 healthy volunteers. The subjects will receive 14C-R924548 as an oral suspension.

Intervention

Study Medication
Active substance: R548
Activity: janus kinase 1 (JAK1) and janus kinase 3 (JAK3)
Dosage form: aqueous suspension or aqueous solution

Treatment:
a single oral dose of 400 mg 14C-R548 aqueous suspension on Day 1

Discharge will occur on Day 8 if the Total Radioactivity Discharge Criteria are met, or as late as Day 12.
Discharge criteria:
1. The concentration of radioactivity in 2 consecutive whole blood and plasma timepoints is below the Lower Limit of Quantification (LLOQ) AND
2. * 90% of the administered dose is recovered in the excreta OR
3. * 90% of the dose is recovered in the excreta but the results have shown * 1% of administered radioactive dose is present in the excreta for at least 2 consecutive days.

Study burden and risks

Not applicable

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
18-55 years of age
BMI 18.0-31.0 kg/m2

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS.
Participation in another drug study within 3 months before the start of this study.
Blood donation within 3 months from the start of this study or in case you have donated more than 1.5 liters of blood in the 10 months before the start of this study.

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):	28-06-2012
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO Date:	19-06-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-06-2012
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	EUCTR2012-002570-31-NL
CCMO	NL40981.056.12