A Phase 1, Randomized, Single-Center Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of Single and Multiple Doses of R948835 in Healthy Subjects

Published: 12-03-2018
Last updated: 12-04-2024

Primary objectives:Part A: To investigate the safety and tolerability of single ascending oral doses of R835 in healthy subjects.Part B:To investigate the safety and tolerability of multiple ascending oral doses of R835 in healthy subjects.Part C:...

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

Summary

ID

NL-OMON48536

Source
ToetsingOnline

Brief title
CS0292 (C-948835-001)

Condition

- Other condition
- Autoimmune disorders

Synonym
autoimmuun and inflammatory conditions

Health condition

Inflammatory conditions

Research involving

Human

Sponsors and support

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

Intervention

Keyword: pharmacokinetic, safety, tolerability

Outcome measures

Primary outcome

Part A

* Safety and tolerability parameters include: physical examination, AEs,

clinical laboratory values, vital signs, and 12-lead ECG.

Part B

* Safety and tolerability parameters include: physical examination, AEs,

clinical laboratory values, vital signs, and 12-lead ECG.

Part C

* Pharmacodynamic parameters include: AUEC, Cmax and tmax of CRP, TNF-*, IL-6,

IL-8 , MIP1a and MIP1b over 24 hours after LPS challenge.

Secondary outcome

Part A

* Pharmacokinetic parameters include: Cmax, tmax, t1/2, AUC0-t, AUC0-*, Cavg,

CL/F, and Vz/F.

Part B

* Pharmacokinetic parameters include: Cmax, tmax, t1/2, AUC0-t, AUC0-*,

AUC0-tau, Cavg, CL/F, and Vz/F.

* Pharmacokinetic parameters for caffeine (Cohort B2 only): Cmax, tmax, t1/2,

AUC0-t, and AUC0-*.

Part C

* Pharmacokinetic parameters include: Cmax, tmax, t1/2, AUC0-t, AUC0-*, Cavg,

CL/F, and Vz/F.

Study description

Background summary

Rigel Pharmaceuticals, Inc.is developing R948835 for the treatment of autoimmuno and inflammatory conditions

Study objective

Primary objectives:
Part A: To investigate the safety and tolerability of single ascending oral doses of R835 in healthy subjects.
Part B:To investigate the safety and tolerability of multiple ascending oral doses of R835 in healthy subjects.
Part C: To characterize the pharmacodynamic (PD) profile of R835 following a lipopolysaccharide (LPS) challenge in healthy subjects.

Secondary objectives:
Part A: To characterize the pharmacokinetic (PK) profiles of single oral doses of R835 and its metabolite R941466.
Part B: To characterize the PK profiles of multiple oral doses of R835 and its metabolite R941466.
Part B2: To evaluate the potential for R835-mediated inhibition of caffeine metabolism, a CYP1A2 substrate.
Part C: To characterize the PK profiles of R835 following a LPS challenge.

Study design

This study is a randomized, double-blind, placebo-controlled Phase 1 study in three parts: single ascending doses (Part A), multiple ascending doses (Part B) with caffeine interaction on selected dose (Cohort B2 only), and single dose with LPS challenge (Part C).

Intervention

R948835
Matching placebo

Study burden and risks

This study is being conducted in healthy volunteers. There are no anticipated benefits of the IMP. Please see the IMP information (IB) for further information.

Contacts

Public
Rigel Pharmaceuticals, Inc.

1180 Veterans Blvd na
na 94080
US
Scientific
Rigel Pharmaceuticals, Inc.

1180 Veterans Blvd na
na 94080
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy male and females (18 till 55 years including)

Exclusion criteria

Clinical significant abnormalities at medical research

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):	19-04-2018
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	30-03-2018
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-09-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-09-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	05-12-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-12-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-01-2019

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	EUCTR2018-000619-26-NL
CCMO	NL65180.056.18

Study results

Results posted: 22-04-2020

First publication
05-12-2019