A randomized, adaptive, investigator/subject blind, single ascending dose, placebo-controlled phase I study to investigate the safety, tolerability, pharmacokinetics, and pharmacodynamics of subcutaneously administered RO7049665 in healthy volunteers.

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

Summary

ID

NL-OMON47456

Source
ToetsingOnline

Brief title
RO7049665 FIM SAD study.

Condition

- Autoimmune disorders

Synonym
Auto immune diseases

Research involving
Human

Sponsors and support

Primary sponsor: Hoffmann-La Roche
Source(s) of monetary or material Support: Farmaceutische Industrie

Intervention

Keyword: Diabetic type 1, multiple sclerosis (MS), Psoriasis

Outcome measures

Primary outcome

To evaluate the safety and tolerability of single-ascending doses of

subcutaneous (SC) injections of RO7049665 in healthy volunteers.

Secondary outcome

To investigate the single dose pharmacokinetics of RO7049665 in healthy

volunteers.

Study description

Background summary

RO7049665 is a new investigational compound that may eventually be used for the treatment of chronic autoimmune diseases like type 1 diabetes (T1D), rheumatoid arthritis (RA), psoriasis, multiple sclerosis (MS) and inflammatory bowel disease (IBD) like ulcerative colitis and Crohn*s disease (CD). In these diseases, the immune system reacts in an abnormal way to a normal body part. RO7049665 is designed to boost the parts of the immune system which are believed to combat auto-immune disease (regulatory T-cells or Treg), without stimulating or damaging those parts of
the immune system which are not involved. It is designed to have fewer side effects than similar, currently available products.
This is the first time that this study compound will be given to humans.

Study objective

The purpose of the study is to investigate to what extent RO7049665 is tolerated. It will also be investigated how quickly and to what extent RO7049665 is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of RO7049665 on specific white blood cells (regulatory T cells, also called Treg) will be investigated (this is called pharmacodynamics).

This study will be performed in approximately 70 (but no more than 100) healthy male volunteers, divided over approximately 10 groups.

This study is not intended to improve the health, but is necessary for the further development of RO7049665.

Study design

The actual study will consist of 1 period during which the volunteers will stay in the clinical research center in Groningen (location UMCG) for 7 days (6 nights) followed by 7 days during which they will visit the clinical research center in Groningen (location UMCG) for a short visit.

They are expected at the clinical research center at 14:00 h in the afternoon prior to the day of administration of the study compound. They will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).

They will leave the clinical research center on Day 6 (Day 1 is the day of administration of the study compound). They will have to return for short visits in the morning on Day 8, 12, 15, 21, 29, 43 and 57. The follow-up visit will take place on Day 57.

Your participation to the entire study, from the pre-study screening until the follow-up visit, will be a maximum of 90 days (approximately 13 weeks).

Intervention

Group - Treatment
1 RO7049665 1.5 µg* or placebo
2 RO7049665 5 µg or placebo
3 RO7049665 16 µg or placebo
4 RO7049665 55 µg or placebo
5 RO7049665 190 µg or placebo
6 RO7049665 650 µg or placebo
7 RO7049665 2200 µg or placebo

8 RO7049665 7500 µg or placebo
9 RO7049665 XXXX µg or placebo
10 RO7049665 XXXX µg or placebo

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection.
Update per protocol version 2: In previous groups (group 1 to 7), skin rash was reported.

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 subjects
18 - 45 years, inclusive
BMI 18.0 - 30.0 kg/m2
non smokers

Exclusion criteria

Suffering from hepatitis B, hepatitis C, 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 within 60 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:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	06-06-2017
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-06-2017
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-05-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-05-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-06-2018
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2018
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	EUCTR2017-000884-34-NL
CCMO	NL62024.056.17