A Phase 1, Randomized, Double-Blind, Placebo-Controlled, Single and Multiple-Ascending Dose Study of FPA008 in Healthy Volunteers and Subjects with Rheumatoid Arthritis

Published: 30-09-2013
Last updated: 24-04-2024

The purpose of the study is to investigate to what extent FPA008 is safe and tolerated, specifically what side effects the drug (FPA008) may have at different dose levels, when given intravenously over approximately 30 minutes. The study will also...

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

Summary

ID

NL-OMON40412

Source
ToetsingOnline

Brief title
Phase 1 SD, MD in HV and RA patients

Condition

- Autoimmune disorders

Synonym
rheuma, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Five Prime Therapeutics, Inc.
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: First in Men, IgG4 monoclonal antibody, Rheumatoid Arthritis

Outcome measures

Primary outcome

To assess safety and tolerability of single and multiple doses of FPA008 in

healthy volunteers and in rheumatoid arthritis subjects.

Secondary outcome

* To characterize the pharmacokinetic profile of FPA008 when administered as a

single dose (Part 1 only) or a multi-dose regimen (Parts 2 and 3).

* To assess pharmacodynamic responses to FPA008 administration in healthy

volunteer subjects and rheumatoid arthritis subjects.

Study description

Background summary

FPA008 is a new investigational compound that may eventually be used for the treatment of rheumatoid arthritis and possibly for other immune mediated disorders. The study is performed to gain insight in the side effects of the drug administered at different dose levels.

Study objective

The purpose of the study is to investigate to what extent FPA008 is safe and tolerated, specifically what side effects the drug (FPA008) may have at different dose levels, when given intravenously over approximately 30 minutes. The study will also investigate how quickly FPA008 circulates and eliminated from the body. In addition, the effect of FPA008 on immune response and bone turnover will be investigated by assessing the extent of change in certain

protein levels in blood and urine. In this study the possible development of antibodies against FPA008 in your blood will be investigated.

Study design

Part 1: Randomized, placebo-controlled, single-dose, sequential ascending FPA008 dose cohorts in healthy volunteer subjects.
a) Planned dose cohorts are 0.2 mg/kg, 1 mg/kg, 3 mg/kg, 10 mg/kg (or alternative dose), and possibly higher (up to 20 mg/kg) based on safety, PK, and PD data.
b) Each dose cohort will start with 2 sentinel subjects (1 active and 1 placebo), who will be observed for 24 hours prior to enrolling the remainder of the cohort.

Part 2: Randomized, placebo-controlled, dual-dose (q 14 days), sequential ascending FPA008 dose cohorts in healthy volunteer subjects.
a) Planned dose cohorts are 1 mg/kg, 3 mg/kg, 10 mg/kg, and possibly higher (up to 20 mg/kg) based on safety, PK, and PD data.
b) The first dose cohort will initiate once safety has been cleared in Part 1.

Intervention

During part 1 the volunteers will receive a single ascending dose of FPA008, during part 2 a multiple ascending dose. Each group of volunteers will be divided into 2 subgroups. The first 2 volunteers will be dosed on the same day (one with FPA008 and one with placebo [inactive formulation]). After dosing, the safety and tolerability of FPA008 in these volunteers will be closely monitored for at least 24 hours. If there are no concerns about the safety and tolerability, the next day the remaining 6 volunteers will be dosed (5 with FPA008 and one with placebo).

Study burden and risks

- possible side-effects as described under E9
- venapunctures and canula
- screening and follow-up visit
- admission to the clinic
- study activities: physical examinations, vital signs, ECG, local tolerability
- eye test and eye foto

Contacts

Public

Five Prime Therapeutics, Inc.

Two Corporate Drive 7047
South San Francisco CA 94080
US
Scientific
Five Prime Therapeutics, Inc.

Two Corporate Drive 7047
South San Francisco CA 94080
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

part 1 and 2:
- Healthy adult male and female subjects
- Ages 21*55 years inclusive
- BMI 18-32 kg/m2 inclusive;part 3:
n/a for The Netherlands, will be executed in Eastern Europe

Exclusion criteria

Subjects who have a clinically relevant history or presence of any clinically significant disease or disorder, that in the opinion of the investigator would place the subject at undue risk.

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):	29-10-2013
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	30-09-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	04-10-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-06-2014
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	12-06-2014
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	EUCTR2013-003337-15-NL
CCMO	NL46339.056.13