PHASE I, DOUBLE BLIND, PLACEBO-CONTROLLED, DOSE-ESCALATION STUDY TO ASSESS THE SAFETY, TOLERABILITY, AND PHARMACOKINETICS OF FMX-8 IN HEALTHY MALE VOLUNTEERS

Published: 01-02-2012
Last updated: 26-04-2024

Primary:To determine the safety, tolerability, and pharmacokinetic (PK) profile of single ascending intravenous (iv) doses and of multiple ascending iv doses of FMX-8 in healthy subjectsSecondary:To evaluate the pharmacodynamics (PD) of FMX-8 in...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON37770

Source
ToetsingOnline

Brief title
FMX-8 SAD and MAD study

Condition

- Red blood cell disorders

Synonym
anemia, iron deficiency

Research involving
Human

Sponsors and support

Primary sponsor: FerruMax Pharmaceuticals, Inc
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: FMX-8, pharmacokinetics, safety, tolerability

Outcome measures

Primary outcome

Safety, tolerability of FMX-8 and pharmacokinetics of FMX-8 (serum FMX-8 drug

concentrations, PK parameters)

Secondary outcome

Pharmacodynamic parameters: TBIC (Total iron-binding capacity), UIBC

(Unsaturated iron-binding capacity), TSAT (Transferrin saturation), ferritin,

transferrin, reticulocyte count and reticulocyte hemoglobin content

Study description

Background summary

FMX-8 is a new investigational compound that may eventually be used for the treatment of anemia due to chronic diseases (e.g. cancer and kidney disease). FMX-8 is in the development stage and is not registered as a drug. This is the first time that this compound is being given to humans.

Study objective

Primary:
To determine the safety, tolerability, and pharmacokinetic (PK) profile of single ascending intravenous (iv) doses and of multiple ascending iv doses of FMX-8 in healthy subjects

Secondary:

To evaluate the pharmacodynamics (PD) of FMX-8 in iron parameters

Exploratory:
To evaluate the circulating hepcidin level upon FMX-8 treatment

Study design

A double-blind, placebo-controlled, dose-escalation Phase I study to assess the safety, tolerability, and pharmacokinetics of FMX-8 in healthy male subject.

The study will consist of 2 parts (SAD and MAD part):
In Part 1 (SAD), up to 40 subjects (5 dose groups of 8 subjects) will receive escalating single iv doses (as a 30 minute infusion on Day 1) of FMX-8 or placebo in a ratio of 3:1 (FMX-8:placebo. Dose levels for part 1 will be escalated per group depending on the results of the preceding group. Dose level will start at 0.3 mg/kg FMX-8 and not exceed 30 mg/kg) . Dose levels most likely will be 0.3 mg/kg, 1 mg/kg, 3 mg/kg, 10 mg/kg, and 30 mg/kg.

In Part 2 (MAD), up to 30 subjects (3 dose groups of 10 subjects) will receive a total of 4 iv doses of FMX-8 or placebo in 2 weeks (as 30 minutes infusions on Days 1, 4, 7 and 10) in a ratio of 4:1 (FMX-8:placebo). The initial doses for the MAD will be selected from within the range of doses already tested in the single ascending dose (SAD) cohorts. Tentative dose levels are 0.3 mg/kg, 3 mg/kg and 30 mg/kg
In addition, subjects participating in Part 2 will receive two times (Day 1 and Day 10) a standard iron tablet (a commercially available, over-the-counter brand), containing 325 mg ferrous sulfate, equivalent to 65 mg iron).

Procedures and assessments during the study:
Screening , follow-up and during study: demographics, body weight and height (including body mass index calculation), medical history, drug and alcohol screen, cotinine test, blood sampling for serology (HBsAg, anti HCV and anti-HIV 1/2), clinical chemistry, hematology, coagulation, pharmacokinetics, pharmacodynamics and immunogenicity and Heart trace (ECG*s)

Intervention

The study will consist of 2 parts (SAD and MAD part):

Part 1 (SAD) will consist of 5 dose groups (of 8 subjects), each group will stay in the clinical research centre in Groningen for 5 days (4 nights)

Part 2 (MAD) will consist of 3 dose groups (of 10 subjects) each group will stay in the clinical research centre in Groningen for 14 days (13 nights)

During the study subjects will receive FMX-8 or inactive formulation (placebo) after a fasting period (no food or drinks, except water) of at least 10 hours by an infusion directly into a vein. This infusion will take 30 minutes.
In Part 1 per group 6 participants will receive FMX-8 and 2 participants will receive placebo; the participants will each receive one dose.
In Part 2, per group 8 participants will receive FMX-8 and 2 participants will receive placebo; the participants will each receive four doses of either FMX-8 or placebo.

Whether you will receive the active drug or placebo will be determined by chance. Neither the participant nor the investigator knows if FMX-8 will be dosed

From 1.5 hour after end of the infusion subjects will receive a breakfast. During fasting subjects are allowed to drink water.

Study burden and risks

During the study several assessments will be conducted differing in extent and the nature of burden:

Blood draws will be taken via direct puncture or an indwelling canula: It is anticipated that for part 1, 1 time(s) an indwelling canula will be used and 16 blood draws will be drawn by direct puncture of the vein and for part 2, 2 time(s) an indwelling canula will be used and 37 blood draws will be drawn by direct puncture of the vein.
Studymedication will be administered by an infusion directly into a vein for this purpose an indwelling canula will be inserted, this is in addition to the indwelling canula used for blood sampling. Thus during some dosing occasions subjects will have a canula inserted in both arms. The canula for the infusion will be removed immediately after each dosing.
Possible side effects of an indwelling canula are pain, light bleeding, heamatoma, possibly an infection.

Heart trace (ECG*s) will be made regularly.

See section E9 for a description of the risk related to participation in this study

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
- 18-55 yrs, inclusive
- BMI: 18.0-30.0 kg/m2, inclusive
- non-smoking

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):	14-02-2012
Enrollment:	70
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	CVS Iron 65 mg Tablets
Generic name:	ferrous sulfate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	01-02-2012
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	10-02-2012
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	EUCTR2011-005854-76-NL
CCMO	NL39571.056.12