A phase I, double-blind, randomised, placebo-controlled study, in three parts (parts A, B and C) to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of BIM23B065 administered subcutaneously as single and multiple ascending doses to young healthy male subjects

Published: 12-02-2015
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Objectives:Primary Objective: • To assess the safety and tolerability of single and multiple ascending doses of BIM23B065 when given as a subcutaneous (s.c.) bolus injection in young healthy male subjects.Secondary objectives:• To determine the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Interventional

Summary

ID

NL-OMON41949

Source
ToetsingOnline

Brief title
BIM23B065 in healthy volunteers

Condition

- Hypothalamus and pituitary gland disorders

Synonym
acromegaly, gigantism.

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Ipsen Pharma SAS

Intervention

Keyword: acromegaly, dopamine, dopastatin, somatostatin

Outcome measures

Primary outcome

Safety: Incidence and severity of adverse events, laboratory abnormalities,

changes in ECGs and Vital signs

Secondary outcome

Pharmacokinetic characteristics of BIM23B065 and pharmacodynamic markers

profile (Growth Hormone cycle, Prolactin cycle and Insulin like growth factor-1

levels).

Study description

Background summary

Acromegaly is a syndrome that is the result of an excess growth hormone production in the anterior pituitary gland. The primary goal of treatment is to reduce growth hormone production to normal levels. Current medical treatments are somatostatin analogues and dopamine analogues, which both stop growth hormone production in a different way. BIM23B065 is a drug substance, which works on both dopamine and somatostatin mechanisms and therefore an attractive candidate for the treatment of acromegaly.

Study objective

Objectives:
Primary Objective:
• To assess the safety and tolerability of single and multiple ascending doses of BIM23B065 when given as a subcutaneous (s.c.) bolus injection in young healthy male subjects.
Secondary objectives:
• To determine the maximal administrable dose of single and multiple ascending doses of BIM23B065 when given as a s.c. bolus injection in young healthy male subjects.
• To investigate the pharmacokinetic (PK) profile of single and multiple ascending doses when given by s.c. bolus injection in young healthy male subjects.
• To investigate the pharmacodynamic (PD) markers profile following single and multiple ascending doses when given by s.c. bolus injection in young healthy male subjects.
• To investigate the safety and PK profiles of different volumes of administration during
the titration period.

Study design

The study will be a single-center, double-blind, randomized, placebo-controlled, single ascending dose and multiple ascending dose study to evaluate the safety, tolerability, PK and PD of BIM23B065 when given by s.c. bolus injection in young healthy male subjects.

Intervention

Single or multiple doses of BIM23B065 or placebo.

Study burden and risks

Potential side effects of BIM23B065 injections and potential complaints caused by being fasted, de lifestyle restrictions, the timeinvestments and blood sample collection.

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 yrs, inclusive
- BMI: 19-30 kg/m2, inclusive
- Provision of written informed consent

Exclusion criteria

Any clinically significant disease or condition that could interfere with, or treatment of which might interfere with, the conduct of the study, or that would, in the opinion of the investigator, pose an unacceptable risk to the subject in this study. Positive test at screening of any of the following: Hepatitis B, Hepatitis C or human immunodeficiency virus/AIDS, History of cholelithiasis, or detected at screening gallbladder echography

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):	25-03-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	12-02-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	02-03-2015
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-07-2015
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	03-12-2015
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-12-2015
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	EUCTR2014-004561-24-NL
CCMO	NL52019.056.15