A Single-Center, Phase I, Randomized, Double- Blind, Placebo-Controlled, First-In-Man Trial to Assess the Safety, Tolerability, Immunogenicity, Pharmacokinetics, and Pharmacodynamics of Single Ascending Doses of Subcutaneous MSB0010841 (Anti-IL-17A/F Nanobody) in Healthy Male Subjects

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

Summary

ID

NL-OMON38778

Source
ToetsingOnline

Brief title
MSB0010841 SAD study

Condition

- Autoimmune disorders

Synonym
illness that occurs when the body tissues are attacked by its own immune system

Research involving
Human

Sponsors and support

Primary sponsor: Merck KGaA
Source(s) of monetary or material Support: farmaceutische industrie

Intervention

Keyword: autoimmune diseases, MSB0010841, nanobody

Outcome measures

Primary outcome

Pharmacodynamics : Pharmacodynamics parameters

Pharmacokinetics : Pharmacokinetic parameters

Safety : TEAEs, local tolerability assessment, clinical laboratory and vital

signs

Secondary outcome

n/a

Study description

Background summary

MSB0010841 is an experimental drug that may eventually be used for the treatment of several autoimmune diseases. An autoimmune disease is an illness that occurs when the body tissues are attacked by its own immune system. This occurs for example in rheumatoid arthritis and psoriasis patients.

MSB0010841 is a drug made of 3 so-called nanobodies. A nanobody is a very small fragment of an antibody. Antibodies are produced by our own body for host defense against for example bacteria and viruses. However, antibodies can also be prepared in a custom made way by pharmaceutical companies, so that they can be used for medical research and various therapeutical applications. MSB0010841 is constructed in such a way that it can recognize, bind specifically to and block the function of proteins. These proteins, which are interleukins 17A and 17F, are important factors in autoimmune diseases, including rheumatoid arthritis and psoriasis.

MSB0010841 is experimental, which means that it is not approved yet by the Health Authorities to use as a prescribed drug in clinical practice. This is the first time that this compound is being given to humans.

Study objective

The purpose of this research study is to investigate how safe the compound is and how well the compound is tolerated. The study will also investigate how quickly and to what extent the compound is absorbed and eliminated from the body (this is called pharmacokinetics). In addition, the effect of the compound on the body will be investigated by the evaluation of different biological markers in the blood, in particular interleukin 17A and 17F blood levels (this is called pharmacodynamics).

Study design

Single-center, randomized, double-blind, placebo-controlled, single ascending dose (SAD), first-in-man (FIM) trial in healthy male subjects.

Intervention

Single doses of MSB0010841 will be administered by subcutaneous injection(s) at the following planned dosages:
Cohort 1: 3 mg;
Cohort 2: 12 mg;
Cohort 3: 60 mg;
Cohort 4: 120 mg;
Cohort 5: 240 mg;
Cohort 6: 360 mg

Study burden and risks

- possible side-effect as described under E9
- venapunctures
- subcutaneous injections
- screening and follow-up visit

- admission to the clinic
- study activities: physical examinations, spirometry, vital signs, ECG, holter, telemetry, local tolerability assessment

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,
20.0 - 30.0 kg/m2, inclusive

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):	20-02-2013
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO

Date:	17-01-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	30-01-2013
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-05-2013
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	EUCTR2012-005064-96-NL
CCMO	NL43144.056.13