A Single-Center, Phase I, Randomized, Double-Blind, Placebo-Controlled Trial to Assess the Safety, Tolerability, Immunogenicity, Pharmacokinetics, and Pharmacodynamics of Multiple 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-OMON38479

Source
ToetsingOnline

Brief title
MSB0010841 MAD 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 inflammatory responses in 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.
Interleukin (IL) 17A and IL-17F are important mediators of inflammation in autoimmune diseases, including rheumatoid arthritis and psoriasis. MSB0010841 is designed to specifically recognize, bind and block the function of IL 17A and IL-17F.
Because MSB0010841 is a protein, the body may recognize the drug as foreign. As a result an immune response can occur, for example by making antibodies. The ability of a compound to elicit an immune response is called immunogenicity. The production of antibodies towards the drug may only cause adverse events upon repeated administration. In monkeys only minor allergic reactions were observed upon repeated administrations with MSB0010841. The production of antibodies towards the medication leads to reduced efficacy of the medical product. Therefore it will be investigated whether antibodies are produced after administration of multiple doses of MSB0010841.

MSB0010841 is an experimental drug, which means that it is not yet approved by the Health Authorities to use as a prescribed drug in clinical practice.
However, MSB0010841 has been given to humans before in a study at PRA which is performed simultaneously with this study, i.e., the first dose you receive has already been investigated in this first study.

Study objective

The purpose of this research is to investigate the safety and tolerability of MSB0010841. This study will also investigate how quickly and to what extent the study medication is absorbed and eliminated from the body (this is called pharmacokinetics [PK]). In addition, the effect of MSB0010841 on the body will be investigated by the evaluation of different markers in the blood, IL-17A and IL-17F in particular (this is called pharmacodynamics). This study will also investigate to what extent the body produces antibodies towards MSB0010841 (immunogenicity).

Study design

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

Intervention

Depending on the dose you will receive at least 1 injection and maximally 4 injections per dosing, with a maximum volume of 1 mL per injection.
* Group 1 (18 mg) 1 injection (0.3 mL), 3 injections in total
* Group 2 (60 mg) 1 injection (1 mL), 3 injections in total

* Group 3 (120 mg) 2 injections with 1mL per injection (total of 2mL), 6 injections in total
* Group 4 (240 mg) 4 injections with 1mL per injection (total of 4mL), 12 injections in total

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):	01-08-2013
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	23-05-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	30-05-2013
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	EUCTR2013-001987-40-NL
CCMO	NL44857.056.13