A study investigating the biological availability of ALX-0061, a new drug in the treatment of rheumatoid arthritis, after subcutaneous and intravenous administration in healthy volunteers.

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

Summary

ID

NL-OMON40925

Source
ToetsingOnline

Brief title
ALX-0061 phase I bioavailability study in healthy volunteers.

Condition

- Autoimmune disorders

Synonym
chronic systemic inflammatory disease, rheumatoid arthritis

Research involving
Human

Sponsors and support

Primary sponsor: Ablynx NV
Source(s) of monetary or material Support: Farmaceutische industrie.

Intervention

Keyword: ALX-0061, autoimmune disease, rheumatoid arthritis

Outcome measures

Primary outcome

Primary objective:

To assess the pharmacokinetics of single subcutaneous (s.c.) and intravenous

(i.v.) doses of ALX-0061 in healthy volunteers.

Secondary outcome

Secondary objective:

To assess the pharmacodynamics, safety, tolerability, and immunogenicity of

single s.c. and i.v. doses of ALX-0061 in healthy volunteers.

Study description

Background summary

ALX-0061 is a new investigational compound that may eventually be used for the treatment of rheumatoid arthritis and possibly other immune mediated disorders (such as systemic lupus erythematosus). Rheumatoid arthritis is a chronic systemic inflammatory disease (autoimmune disease), localized primarily in joints of the hands and feet. Patients with rheumatoid arthritis often have elevated blood levels of interleukin-6, a protein which stimulates the inflammatory process leading to joint destruction.
ALX-0061 inhibits the inflammatory effects of interleukin-6. ALX-0061 is protein that consists of several parts (building blocks) that are present in

the human body by nature (a so called *nanobody*). ALX-0061 is currently under development and is not yet registered as a drug, but in a previous study it has been given to patients with rheumatoid arthritis.

Study objective

The purpose of the study is to investigate to what extent ALX-0061 is tolerated. It will also be investigated how quickly and to what extent ALX-0061 is absorbed and eliminated from the body (this is called pharmacokinetics), and how much of the compound is absorbed in the body when administered subcutaneously when compared to an intravenous administration (this is called absolute bioavailability). In addition, the effect of ALX-0061 on the immune response and the extent of inhibition of interleukin-6 will be investigated (this is called pharmacodynamics). For the purpose of the study the possible development of antibodies against ALX-0061 will be investigated in your blood. The development of antibodies against the ALX-0061 may make the drug less effective.

Study design

Day 1 is the day of administration of study medication. The actual study will consist of 1 period during which the volunteers will stay in the clinical research center in Groningen for 4 days (3 nights: from Day -1 to Day 3). They will return for a number of ambulant visits as specified for each treatment group below:

When they participate in Group 1 or 2 (50 mg ALX-0061), they will return for 7 ambulant visits to the clinical research center on Days 4, 6, 8, 11, 18, 25 and 32. Next, they will return for a final post study screening on Day 60.
The participation to the entire study, from pre-study screening until the post study screening, will be maximally 90 days.

When they participate in Group 3 (150 mg ALX-0061), they will return for 9 ambulatory visits to the clinical research center on Days 4, 6, 8, 11, 18, 25, 32, 39 and 46. Next, they will return for a final post-study screening on Day 60.
The participation to the entire study, from pre-study screening until the post study screening, will be maximally 90 days.

When they participate in Group 4 or 5 (300 mg ALX-0061) , they will return for 10 ambulatory visits to the clinical research center on Days 4, 6, 8, 11, 18, 25, 32, 39, 46 and 53. Next, they will return for a post-study screening on Day 83.
The participation to the entire study, from pre-study screening until the post study screening, will be maximally 113 days.

Intervention

The volunteers will receive a single dose of ALX-0061 according to one of the 5 treatment groups below:

Group Day Route of administration Treatment
1 1 intravenously 50 mg ALX-0061
2 1 subcutaneously 50 mg ALX-0061
3 1 subcutaneously 150 mg ALX-0061
4 1 intravenously 300 mg ALX-0061
5 1 subcutaneously 300 mg ALX-0061

Study burden and risks

Registration of adverse effects: During the entire study all adverse effects you report will be documented.

Blood sampling, indwelling cannula:
During this study less than 500 milliliters of blood will be drawn. The blood samples will be drawn by direct puncture of the vein.

Heart trace (ECG): ECGs will be made regularly.

Intravenous (i.v.) administration (Group 1 or 4): For the i.v. administration of study drug on Day 1 you will have an indwelling cannula inserted. The cannula for the i.v. infusion will be removed immediately after dosing.

Subcutaneous injection (Group 2, 3 or 5): On Day 1 of the study you will receive 1 or 2 injections in the skin of the abdomen

Injection Site Reaction: A nurse will examine the injection site several times during the study by using the injection site reaction score list.

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 or female volunteers
Age between 18 and 55 years
BMI between 18.0 - 30.0 kg/m2

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

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-03-2014
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	13-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-03-2014
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	EUCTR2013-005493-21-NL
CCMO	NL48280.056.14