'A phase 1 study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of single-dose intravenous and subcutaneous administration and multiple-dose subcutaneous administration of OMS906 in healthy subjects'

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The purpose of this study is to investigate how safe the new compound OMS906 is and how well it is tolerated when it is administered to healthy volunteers. OMS906 has not been administered to humans before. It has been previously tested in the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Red blood cell disorders
Study type	Interventional

Summary

ID

NL-OMON49225

Source
ToetsingOnline

Brief title
Safety and PK of OMS906 in healthy volunteers.

Condition

- Red blood cell disorders

Synonym
blood disease that causes red blood cells to break apart

Research involving
Human

Sponsors and support

Primary sponsor: Omeros Corporation
Source(s) of monetary or material Support: Faramaceutische Industrie

Intervention

Keyword: Bexsero, Blood disease, Nimenrix, OM906

Outcome measures

Primary outcome

Part A: Single Ascending Dose (SAD)

• To assess the safety and tolerability of OMS906, when administered as single ascending IV and SC doses in healthy subjects.

Part B: Multiple Ascending Dose (MAD)

• To assess the safety and tolerability of OMS906, when administered as multiple ascending SC doses in healthy subjects.

Secondary outcome

Part A: SAD

• To characterize the PK of OMS906, when administered as single ascending IV and SC doses in healthy subjects.

• To characterize the PD of OMS906, when administered as single ascending IV and SC doses in healthy subjects.

• To assess the presence of anti-drug antibodies (ADA) against OMS906 after single ascending IV and SC doses in healthy subjects.

Part B: MAD

• To characterize the PK of OMS906, when administered as multiple ascending SC doses in healthy subjects.

• To characterize the PD of OMS906, when administered as multiple ascending SC doses in healthy subjects.

• To assess the presence of ADAs against OMS906 after multiple ascending SC doses in healthy subjects.

Study description

Background summary

OMS906 is a new compound that may eventually be used for the treatment of paroxysmal nocturnal hemoglobinuria (PNH). PNH is a rare, acquired, disease of the blood characterized by destruction of red cells by the complement system, a part of the body's immune system. PNH arises when a mutation occurs in a bone marrow stem cell. Stem cells give rise to all the blood cells including red blood cells which carry oxygen, white blood cells which fight infection and platelets which are involved in forming blood clots. The mutation in the affected stem cell passes to all three types of blood cells in bone marrow resulting in anemia, blood clots, a reduced ability to fight infection and the presence of blood in urine produced overnight, which gives the disease its name.

OMS906 is a humanized monoclonal antibody targeting the enzyme which is the key activator of the alternative pathway of complement (where there are two pathways, "classical" and "alternative"). Antibodies work by binding to proteins in the body so that the harmful effect of that protein is removed. OMS906 binds to proteins involved in a specific part of the immune system called mannan-binding lectin-associated serine protease3 (MASP-3). Laboratory studies have shown that this action reduces the breakdown of red blood cells. OMS906 does not interfere with the classical complement pathway, which is a critical component of the immune response to infection.

Study objective

The purpose of this study is to investigate how safe the new compound OMS906 is and how well it is tolerated when it is administered to healthy volunteers.

OMS906 has not been administered to humans before. It has been previously tested in the laboratory and on animals. OMS906 will be tested at various dose levels. This study will be performed in up to 80 healthy volunteers. The study will be performed in 2 parts, Part A and
Part B.

Part A of the study will consist of up to 8 groups of 8 volunteers each. The volunteers can participate in one of these groups. It will also be investigated how quickly and to what extent OMS906 is absorbed and eliminated from the body. In addition, the effect of OMS906 on specific processes in your body will be investigated. The effects of OMS906 will be compared to the effects of a placebo. Please note that when the term *study compound* is used in this document, this can refer to OMS906, placebo, or both.

Part B of the study will consist of 2 groups of 8 volunteers each. The volunteers can participate in one of these groups.

Study design

Part A:
The volunteer will receive OMS906 or placebo as either an intravenous drip or an injection under the skin. The IV infusion lasts approximately 30 minutes. The SC dose is injected into the thigh and lasts only a few seconds or as an infusion into the thigh that lasts approximately 30 minutes. Whether one gets OMS906 IV or SC depends on the Group in which one participates. One dose of the study drug will be given, which will be administered on Day 1.

Whether one is given OMS906 or placebo is determined by drawing lots. 6 volunteers per group receive OMS906 and 2 volunteers receive placebo. Both the volunteer and the responsible physician do not know whether they are receiving OMS906 or placebo.

The actual research consists of 1 period in which one will stay in the research center. This is followed by additional visits to the research center.

Part B:
OMS906 or placebo is given as an injection under the skin (SC: subcutaneous). The SC dose is injected into the thigh and lasts only a few seconds, or as an infusion into the thigh that lasts approximately 30 minutes. The study drug is administered a total of 3 times at 2-week intervals, ie on Day 1, 15 and 29. Whether the volunteer is given OMS906 or placebo is determined by drawing lots.

6 volunteers per group receive OMS906 and 2 volunteers receive placebo. Both the volunteer and the responsible physician do not know whether you are receiving OMS906 or placebo.

The actual research consists of 3 periods in which one will stay in the

research center. The research center is left at least 168 hours (7 days) after dosing. Between the periods and after the last administration, one returns to the research center for 9 outpatient visits. The planned duration of periods, day (s) of departure and itinerant visits can be adjusted depending on new research results.

Intervention

Part A:
1 OMS906 or placebo 0.1 mg / kg ** IV infusion
2 OMS906 or placebo 0.3 mg / kg ** IV infusion
3 OMS906 or placebo 1.0 mg / kg ** IV infusion
4 OMS906 or placebo 3.0 mg / kg ** IV infusion
5 OMS906 or placebo 3.0 mg / kg ** SC injection or infusion
6 OMS906 or placebo 5.0 mg / kg ** SC injection or infusion
7 OMS906 or placebo 8.0 mg / kg ** SC injection or infusion
8 OMS906 or placebo 8.0 mg / kg ** IV infusion
Part B
1 Day 1, 15, and 29 OMS906 or placebo xx mg SC injection or infusion
2 Day 1, 15 and 29 OMS906 or placebo yy mg SC injection or infusion

Study burden and risks

Drawing blood and/or insertion of the indwelling cannula may be painful or cause some bruising.
In total, we will take about 400 milliliters (mL) of blood from the volunteers over several weeks. This amount does not cause
any problems in adults. Based on the discretion of the responsible doctor, extra samples might be taken to guarantee the safety of the participants. If this happens, the total amount of blood drawn will be more than this.

To make a heart tracing, electrodes will be pasted at specific locations on the arms, chest and legs. To monitor the heart rate, electrodes will be pasted at specific locations on the chest and abdomen. Prolonged use of these electrodes can cause skin irritation. A sample will be taken from the back of the nose to test for the presence of meningococci.

We will use a cotton swab for this. Taking the sample only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the nose may cause the volunteers to experience a stinging sensation and their eyes may become watery.

Samples for the coronavirus test will be taken from the back of the nose and throat using swabs. Taking the samples only takes a few seconds, but can cause discomfort and can give an unpleasant feeling. Taking a sample from the back of the throat may cause the volunteer to gag. When the sample is taken from the

back of the nose, they may experience a stinging sensation and their eyes may become watery.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Sex : male or female.
2. Age : 18 to 54 years, inclusive, at Screening.
3. Body mass index : 22.0 kg/m2 to 30.0 kg/m2 inclusive.
4. Status : healthy subjects.

Exclusion criteria

1. Previous participation in the current study.
2. Employee of PRA or the Sponsor, or their immediate family member. Immediate family is defined as current spouse, parent, natural or legally adopted child (including a stepchild living in the household), grandparent, or grandchild of Omeros or PRA employee.
3. History of relevant drug and/or food allergies (this includes known allergies for antimeningococcal antibiotic treatment 19).
4. Using tobacco products within 30 days prior to the Screening.
5. History of alcohol abuse or drug addiction (including soft drugs like cannabis products) within 3 years of Screening.

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:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	01-07-2020
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

	(Assen)
Approved WMO Date:	07-09-2020
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	EUCTR2020-001900-40-NL
CCMO	NL74479.056.20