A Phase 1 Double-Blind, Placebo-Controlled, Single- and Multiple-Dose Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Subcutaneous Nipocalimab in Healthy Male and Female Participants.

Published: 21-04-2021
Last updated: 25-03-2025

In this study we will investigate how safe the new compound nipocalimab is and how well it is tolerated when it is used by healthy participants.We also investigate how quickly and to what extent nipocalimab is absorbed, transported, and eliminated...

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

Summary

ID

NL-OMON50999

Source
ToetsingOnline

Brief title
Evaluation of safety,tolerability,PK and PD of subcutaneous Nipocalimab

Condition

- Autoimmune disorders

Synonym
Autoimmune- and inflammatory diseases

Research involving
Human

Sponsors and support

Primary sponsor: Janssen-Cilag
Source(s) of monetary or material Support: Pharmaceutical Industry

Intervention

Keyword: Nipocalimab, Pharmacodynamics, Pharmacokinetics, Subcutaneous

Outcome measures

Primary outcome

To evaluate the safety and tolerability of single and multiple doses of nipocalimab following SC administration compared with IV administration in healthy participants.

Secondary outcome

To evaluate the PK of single and multiple doses of nipocalimab following SC administration compared with IV administration in healthy participants.

To evaluate the PD effect of nipocalimab on IgG following SC administration compared with IV administration in healthy participants.

To evaluate the antidrug antibody response of nipocalimab following SC administration compared with IV administration in healthy participants.

Study description

Background summary

Nipocalimab is a compound that may potentially be used for the treatment of autoimmune and inflammatory diseases caused by a specific kind of antibody, called IgG antibodies. Nipocalimab is an antibody that binds to a protein that is called the neonatal Fc receptor. This Fc receptor can be found on many cell types of the human body, such as white blood cells and cells in the kidney and the liver. The neonatal Fc receptor is involved in transport of IgG antibodies and inhibition of breakdown of these IgG antibodies. In autoimmune diseases there are *wrong* IgG antibodies that are involved in the disease process. The compound nipocalimab is able to bind the neonatal Fc receptor leading to an increased degradation of all IgG antibodies. It is hoped that this will ultimately lead to the treatment of autoimmune diseases with *wrong* IgG antibodies.

Study objective

In this study we will investigate how safe the new compound nipocalimab is and how well it is tolerated when it is used by healthy participants.

We also investigate how quickly and to what extent nipocalimab is absorbed, transported, and eliminated from the body. The effect of the route of administration is also investigated. In addition, we look at the effect of nipocalimab on IgG, IgA, IgM, and IgE levels, albumin levels, and possibly the amount of binding of nipocalimab to proteins in the serum.

We compare the effects of nipocalimab with the effects of a placebo.

Nipocalimab has been used by humans before. In addition, it has been extensively tested in the laboratory and on animals. Nipocalimab will be tested at various dose levels.

Study design

Part 1:
For the study it is necessary that the volunteer stays in the research center for 1 period of 9 days (8 nights). This will be followed by 5 short visits to the research center.
In Groups 1 to 4, the volunteer will be given nipocalimab or placebo once subcutaneous. Up to 4 separate injections may be given for the subcutaneous administration, each given at a different injection site.
In Groups 5 and 6, the volunteer will be given nipocalimab or placebo once as an intravenous infusion.
In optional Groups 7 and 8, the volunteer will be given nipocalimab or placebo once via a subcutaneous administration via a syringe pump.
Per group, 6 participants receive nipocalimab and 2 participants receive placebo.

Part 2 Group 9a and 9b:
For the study it is necessary that the volunteer stays in the research center 2 periods of 9 days (8 nights). Period 1 will be followed by 3 short visits to the research center. Period 2 will be followed by 4 short visits to the research center.
The volunteer will be given nipocalimab or placebo four times as an injection under the skin (subcutaneous).
Per group, 5 participants will receive nipocalimab and 1 participant will receive placebo.

Part 2 Group 10a and 10b: (Groups 10a and 10b are optional)
For the study it is necessary that you stay in the research center 2 periods of 9 days (8 nights). Period 1 will be followed by 5 short visits to the research center. Period 2 will be followed by 4 short visits to the research center.
The volunteer will be given nipocalimab or placebo four times as an injection under the skin (subcutaneous).
Per group, 5 participants will receive nipocalimab and 1 participant will receive placebo.

Intervention

N/A

Study burden and risks

Possible Side effects:

The study compound may also have (serious) side effects that are still unknown. In addition to unknown side effects, there is a (small) chance that an allergic reaction will occur. This can be caused by the study compound or other ingredients that are used to prepare the formulation.

Possible discomforts:
Blood draw
Drawing blood may be painful or cause some bruising. The use of the indwelling cannula (a tube in a vein in the arm) can sometimes lead to inflammation, swelling, hardening of the vein, blood clotting, and bleeding in the environment (bruising) of the puncture site. In some individuals, a blood draw can sometimes cause pallor, nausea, sweating, low heart rate, or drop in blood pressure with dizziness or fainting.

In total, we will take about 510 milliliters (mL) (Group 9a and 9b) or 550 mL (Group 10a and 10b) of blood from the volunteer. This amount does not cause any problems in adults. To compare: a blood donation involves 500 mL of blood being taken each time. If the investigator thinks it is necessary for the safety of a participant, extra samples might be taken for possible additional testing. If

this happens, the total amount of blood drawn will be more than the amount indicated above.

Heart tracing
To make a heart tracing, electrodes (small, plastic patches) will be placed at specific locations on your arms, chest and legs. Prolonged use of these electrodes can cause skin irritation (rash and itching).

Coronavirus test
Samples for the coronavirus test will be taken from the back of the volunteers 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 volunteers throat may cause him to gag. When the sample is taken from the back of his nose, he may experience a stinging sensation and his eyes may become watery.

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 on the basis of physical examination, medical history, vital signs, and 12-lead electrocardiogram (ECG) performed at screening
- Healthy on the basis of clinical laboratory tests performed at screening
- Continuous non-smoker
- A woman of childbearing potential must have a negative pregnancy test
- It is recommended that participants are up to date on all age appropriate vaccinations prior to screening as per routine local medical guidelines

Exclusion criteria

- Has a history of liver or renal insufficiency; cardiac, vascular, pulmonary, gastrointestinal, endocrine, neurologic, hematologic, rheumatologic, psychiatric, or metabolic disturbances
- Currently has a malignancy or has a history of malignancy within 3 years before screening
- Known allergies, hypersensitivity, or intolerance to nipocalimab or its excipients
- Has received a live vaccine within 3 months prior to screening or has a known need to receive a live vaccine during the study, or within at least 3 months after the last administration of study intervention in this study
- Shows evidence of an active or chronic hepatitis B infection

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:	Completed
Start date (anticipated):	25-05-2021
Enrollment:	60
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	N/A
Generic name:	Nipocalimab

Ethics review

Approved WMO Date:	21-04-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	21-05-2021
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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	EUCTR2020-005892-10-NL
CCMO	NL77410.056.21

Study results

Date completed: 26-05-2022

Results posted: 12-12-2023

URL result
URL
Type
int
Naam
M2.2 Samenvatting voor de leek
URL

Internal documents
File