A single-center, open-label study to evaluate the absorption, distribution, metabolism and excretion (ADME) and pharmacokinetics of LNP023 following a single oral dose of [14C]LNP023 in healthy male/female subjects.

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

Summary

ID

NL-OMON48316

Source
ToetsingOnline

Brief title
ADME of LNP023 following a single oral dose of [14C]LNP023

Condition

- Autoimmune disorders

Synonym
auto-immune diseases

Research involving

Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: ADME, autoimmune diseases, LNP023

Outcome measures

Primary outcome

To characterize the plasma pharmacokinetics (PK) of LNP023 and key metabolites, if applicable.

To determine the PK of total radioactivity in blood and plasma.

To determine the rates and routes of excretion of [14C]LNP023-related radioactivity, including mass balance of total drug-related radioactivity in urine and feces following a single 100-mg oral dose of [14C]LNP023 in healthy volunteers (HV).

Secondary outcome

To assess the safety and tolerability of a single 100-mg oral dose of [14C]LNP023 administered to HV.

Study description

Background summary

LNP023 is a new compound that may eventually be used for the treatment of autoimmune diseases, by influencing the alternative pathway of the complement system. This pathway plays an important role in the immune system*s natural defense against microorganisms. However, hyperactivity of the alternative pathway is known to cause and/or worsen a wide number of diseases with

autoimmune components. LNP023 is a novel compound that inhibits a certain factor in the alternative pathway, and thereby has the potential to treat patients with diseases that are driven by this route of the complement system. This would represent a major unmet medical need.

Study objective

The purpose of this study is to investigate how quickly and to what extent LNP023 is absorbed, broken down, and eliminated from the body (this is called pharmacokinetics). LNP023 will be labelled with 14 carbon (14C) and is thus radioactive. In this way LNP023 can be traced in blood, urine, and feces. LNP023 has been administered to humans before. It has also been previously tested in the laboratory and on animals.

It will also be investigated how safe the new compound LNP023 is and how well it is tolerated when it is administered to healthy volunteers.

Furthermore, the effect of your genetic information on your body*s response to LNP023 will be investigated (this is called pharmacogenetics). This is a mandatory part of this study.

Study design

The participation from screening until the follow-up visit will last up to 8.5 weeks.

The volunteers will once receive 100 milligram (mg) of 14C-labeled LNP023 as an oral capsule with 240 milliliters (mL) of (tap) water. This amount contains 3.7 MBq (100 µCi) radioactivity. One of the investigators will inspect the hands and mouth after intake of the study treatment. All subjects will receive the same study treatment.

The study will consist of 1 period during which the volunteers will stay in the research center for 11 days (10 nights).

Day 1 is the day of administration of the study treatment. They are expected at the research center at 14:00 h in the afternoon prior to the day of administration of the study treatment, so on Day -1. They will leave the research center on Day 10 of the study.

During their stay, the urine and feces will be collected each day to measure the amount of radioactivity in urine and feces. The volunteers should be aware that when the amount of radioactivity in urine and feces is still above pre-defined levels on Day 10, they will have to return to the research center for a maximum of 4 additional overnight visits for 24-hour collection of urine and feces, and for blood sampling.

Intervention

Not applicable.

Study burden and risks

Pain, minor bleedings, bruises, possibly an infection. This study involves using radioactive markers. The additional amount of radiation you will be exposed to in this study is 0.07 mSv (millisievert [unit to measure radiation]). To compare: the background radiation in the Netherlands is ~2.5 mSv per year. The additional radiation you will be exposed to in this study is thus ~3% compared to the average yearly annual radiation burden and is considered acceptable.

Contacts

Public
Novartis

Lichtstrasse 35
Basel CH-4056
CH
Scientific
Novartis

Lichtstrasse 35
Basel CH-4056
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy male / female of non-childbearing potential
18 - 55 years
more than 50 kilograms.
BMI 18.0 - 30.0 kilograms / meter2

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):	17-06-2019
Enrollment:	6
Type:	Actual

Ethics review

Approved WMO

Date:	17-06-2019
Application type:	First submission

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-06-2019
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	EUCTR2019-001407-20-NL
CCMO	NL70000.056.19