An open-label, non-randomized extension study to evaluate the long-term efficacy, safety and tolerability of iptacopan (LNP023) in subjects with C3 glomerulopathy or idiopathic immune-complex-membranoproliferative glomerulonephritis

Published: 20-12-2022
Last updated: 10-01-2025

This study has been transitioned to CTIS with ID 2023-509343-27-00 check the CTIS register for the current data. Participants enrolling from study CLNP023B12301 or CLNP023B12302• Primary Objective: To evaluate the long-term safety and tolerability...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Nephropathies
Study type	Interventional

Summary

ID

NL-OMON56390

Source
ToetsingOnline

Brief title
CLNP023B12001B

Condition

- Nephropathies

Synonym
Complement Kidney Disease, Nephropathy

Research involving
Human

Sponsors and support

Primary sponsor: Novartis
Source(s) of monetary or material Support: Novartis Pharma B.V. (sponsor/verrichter van dit onderzoek)

Intervention

Keyword: C3 Glomerulopathy, Chronic Kidney Disease, iptacopan, LNP023

Outcome measures

Primary outcome

• Primary Efficacy Objective (Cohort A - native C3G): To characterize the

effect of treatment with iptacopan on a composite renal endpoint at the 9-month

visit

• Primary Safety Objective: To evaluate the long-term safety and tolerability

of iptacopan in participants with C3G

Secondary outcome

• To assess the effect of treatment with iptacopan on a 2-component composite

renal endpoint at the 9-month visit

• To assess the long-term effect of iptacopan on renal function in C3G

participants at the 9-month visit

• To assess the effect of iptacopan on proteinuria in C3G participants at the

3-month visit

• To describe the status of C3G disease progression based on glomerular

histopathology in a renal biopsy at the 6- to 9-month visit

• To evaluate the long-term effect of iptacopan on C3 at the 9-month visit

• To assess the longer-term (>9 months of treatment in CLNP023B12001B) effects

of iptacopan on the composite renal endpoint, renal function and C3 in C3G

participants

• To evaluate the pharmacokinetics of iptacopan in participants with prolonged

treatment

Study description

Background summary

The primary purpose of this extension study is to collect and evaluate long-term efficacy, safety and tolerability data in eligible participants receiving open-label iptacopan (LNP023) after completing treatment in the C3G Phase 2 proof of concept (PoC) study CLNP023X2202, C3G Phase 3 study CLNP023B12301 or IC-MPGN Phase 3 study CLNP023B12302. Efficacy and safety assessments at the 9- month visit of this extension study in combination with data from CLNP023X2202 (baseline plus 3 months of treatment) allowed evaluation of the effects of iptacopan on potential endpoint(s) at 12 months of iptacopan treatment in C3G participants. The enrollment of C3G and IC-MPGN participants (adults and adolescents) from Phase 3 studies CLNP023B12301 and CLNP023B12302 permits long-term evaluation of the persistence of effects observed after iptacopan treatment up to 12 months. These longer-term efficacy and safety assessments may be used as supportive information for registration purposes.

Study objective

This study has been transitioned to CTIS with ID 2023-509343-27-00 check the CTIS register for the current data.

Participants enrolling from study CLNP023B12301 or CLNP023B12302
• Primary Objective: To evaluate the long-term safety and tolerability of iptacopan in participants with C3G or IC-MPGN

Study design

CLNP023B12001B is an open-label extension of CLNP023X2202, a Phase 2, open label study evaluating iptacopan in two patient populations with C3G - native kidneys (Cohort A) and kidney transplant with recurrence (Cohort B). Furthermore, all participants completing iptacopan treatment from two ongoing Phase 3 studies were given the option to transition into this extension study:

CLNP023B12301 (C3G) and CLNP023B12302 (IC-MPGN)
Participants completing treatment in the CLNP023X2202, CLNP023B12301 or CLNP023B12302 studies, who want to continue treatment and meet the inclusion/exclusion requirements of the extension study will have the opportunity to receive iptacopan until drug product becomes commercially available and accessible, or the benefit-risk profile is no longer positive, or the program is discontinued for business or strategic reasons.

Intervention

Iptacopan (LNP023) at a dose of 200 mg b.i.d.

Study burden and risks

Demographics, medical history and evaluation of inclusion and exclusion criteria: 1x
Pregnancy test for women of childbearing age: 10x
Vital signs (pulse, blood pressure) and/or body temperature: 9x
Physical examination: 9x
Weight and height: 1x
ECG: 8x
Urine collection: 9x
Mid-stream urine collection: 9x
24-hour urine collection: 1x
Blood tests: 9x
Questionnaires: 2x
Tanner puberty scale: 6x (only in adolescents)
Echocardiography: 1x (only in adolescents)

Contacts

Public
Novartis

Haaksbergweg 16
Amsterdam 1101 BX
NL
Scientific
Novartis

Haaksbergweg 16
Amsterdam 1101 BX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Participants must have completed the treatment period of the CLNP023X2202, or CLNP023B12301 or CLNP023B12302 trial study on study drug.

Exclusion criteria

• Severe concurrent co-morbidities, e.g., advanced cardiac disease (New York Heart Association (NYHA) class IV), severe pulmonary arterial hypertension (WHO class IV), or any illness or medical condition that in the opinion of the investigator and sponsor is likely to prevent the patient from safely tolerating iptacopan or complying with the requirements of the study.
• Participants with an active systemic bacterial, viral or fungal infection within 14 days prior to screening,
or
The presence of fever >= 38C (100.4F) within 7 days prior to screening.
• History of human immunodeficiency virus (HIV) or any other immunodeficiency disease.
• History or current diagnosis of ECG abnormalities indicating significant risk of safety for participants.

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2023
Enrollment:	5
Type:	Actual

Medical products/devices used

Registration:	No
Product type:	Medicine
Brand name:	Nog niet bekend
Generic name:	iptacopan

Ethics review

Approved WMO Date:	20-12-2022
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	26-01-2023
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-04-2023
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-08-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-03-2024
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-04-2024
Application type:	Amendment
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
EU-CTR	CTIS2023-509343-27-00
EudraCT	EUCTR2018-004253-24-NL
ClinicalTrials.gov	NCT03955445
CCMO	NL82423.056.22