A Long-Term Extension of the ARGX-117-2002 Trial to Evaluate the Long-term Safety and Tolerabillity, Efficacy, Pharmacodynamics, Pharmacokinetics, and Immunogenicity of ARGX-117 in Adults with Multifocal Motor Neuropathy

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This study has been transitioned to CTIS with ID 2023-507052-69-00 check the CTIS register for the current data. To evaluate the long-term safety and tolerability of ARGX-117 in adult participants with MMN

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

Summary

ID

NL-OMON53633

Source
ToetsingOnline

Brief title
ARDA+

Condition

- Other condition
- Autoimmune disorders

Synonym

Muscle disease

Health condition

Multifocal Motor Neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: argenx BV
Source(s) of monetary or material Support: industry

Intervention

Keyword: Extention study, MMN, Muscle disease, Phase 2

Outcome measures

Primary outcome

Safety outcomes based on AE monitoring and other safety assessments (clinical

laboratory tests)

Secondary outcome

Modified Medical Research Council (mMRC)

-Value and change from baseline in the mMRC10 sum score

-Proportion of participants showing a deterioration of at least 2 points in

mMRC10 sum score

-Value and change from baseline in the mMRC14 sum score

-Proportion of participants showing a deterioration of at least 2 points in the

mMRC-14 sum score

-Proportion of participants showing a deterioration of 1 or more points in at

least 2 muscle groups as assessed by the mMRC-14 sum score

-Proportion of participants with no deterioration in 2 or more muscle groups as

assessed by mMRC14 sum score

-Value and change from baseline in the average score of the 2 most important muscle groups as assessed by the mMRC-14 sum score

Grip strength (GS)

-Values, change, and percent change from baseline in GS

-Proportion of participants with a decline of >30% in GS

-Proportion of participants with a GS decrease of 8*kilopascals (kPa) or more

Values and change from baseline in the Rasch-built overall disability scale for MMN (MMN*RODS)

Values and change from baseline in the average time for the upper extremity (arm and hand) function (9Hole Peg Test [9-HPT], or timed pegboard test)

Proportion of participants by level of severity on each dimension of EQ-5D-5L

Value and change from baseline in EQ-5D-5L visual analog scale (VAS)

Values and change from baseline in the Chronic Acquired Polyneuropathy Patient-Reported Index (CAP-PRI)

Values and change from baseline in the 9-item Fatigue Severity Scale (FSS)

Values of the Patient Global Impression of Change (PGIC) scale

Proportion of participants by level of severity of MMN as assessed by the Patient Global Impression of Severity (PGIS)

Values for work-related and household chore activities of the Health-Related Productivity Questionnaire (HRPQ) at each visit:

-Hours lost because of absenteeism

-Hours lost because of presenteeism

-Total hours lost

-Percent of scheduled hours lost because of absenteeism

-Percent of scheduled hours lost because of presenteeism

-Percent of scheduled hours lost in total

Serum concentrations and PK parameters for ARGX117

Values and change from baseline in free C2, total C2, and functional complement

activity (CH50) over time

Incidence and prevalence of antidrug antibodies (ADA) against ARGX117

Study description

Background summary

This long-term extension trial serves to evaluate the longterm safety and efficacy of ARGX-117 in adults with multifocal motor neuropathy (MMN).

MMN is a rare neuropathy characterized by progressive asymmetric weakness and atrophy without sensory abnormalities.

Patients with MMN initially respond to the standard of care (SoC), intravenous immunoglobulin (IVIg); however, the disease will continue to progress despite treatment. There is an unmet medical need for an efficacious treatment option with a more favorable safety and tolerability profile and a shorter duration of administration than the current SoC.

ARGX-117, a therapeutic complement-inhibiting antibody that targets complement factor (C2), is being developed to reduce tissue inflammation and attenuate the adaptive immune response by blocking both the lectin and classical complement pathways.

Participants in this long-term extension trial will roll over from the

antecedent trial, ARGX1172002, which evaluated the safety and tolerability, efficacy, pharmacokinetics (PK), pharmacodynamics (PD), and immunogenicity of 3 dose regimens of ARGX-117 administered intravenously (IV) in adult participants with MMN previously stabilized with IVIg.

Study objective

This study has been transitioned to CTIS with ID 2023-507052-69-00 check the CTIS register for the current data.

To evaluate the long-term safety and tolerability of ARGX-117 in adult participants with MMN

Study design

This trial is an extension of the antecedent trial ARGX-117-2002. It is a multicenter trial that has been designed to evaluate the long-term safety and tolerability, efficacy, immunogenicity, PK, and PD of ARGX-117 IV in adults with MMN. The trial will include a double-blinded rollover treatment period (DTP), an open-label treatment period (OTP), and a safety follow-up period.

The investigator, participants, and sponsor trial team (except the sponsor*s clinical trial supplies team) are blinded to the investigational medicinal product (IMP) during the DTP and unblinded during the OTP.

Intervention

IMP administration via infusion, see also ARDA study.

Study burden and risks

1 SAE, 'abces', considered not related to IMP
NO SAE's considered related to blinded treatment
No death or life-threatening events reported

See also safety profile in IB

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

Participants are eligible to be included in the trial only if all of the following criteria apply:
1. Capable of providing signed informed consent, and complying with protocol requirements. Participants must be able to read and write.
2. Must have completed the double-blinded treatment period of the ARGX-117-2002 trial and considered to be eligible for treatment with ARGX-117
3. Agrees to use contraceptive measures consistent with local regulations and the following:
a. Male participants: must use an acceptable contraceptive method that should be maintained at minimum until 15 months after last dose of Investigational Medicinal Product (IMP).
b. Female participants (women) of childbearing potential must have a negative urine pregnancy test at baseline before IMP can be administered.

Exclusion criteria

Participants will be excluded from the trial if any of the following criteria apply:
1. Clinically significant uncontrolled active or chronic bacterial, viral, or fungal infection
2. Clinical evidence of other significant serious diseases, have had a recent major surgery, or who have any other condition, in the opinion of the

investigator, that could confound the results of the trial or put the participant at undue risk.
3. Currently participating in another interventional clinical study
4. Pregnant or lactating or intend to become pregnant during the trial or within 15 months after last dose of the IMP.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-01-2024
Enrollment:	4
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	ARGX-117-IV
Generic name:	ARGX-117-IV

Ethics review

Approved WMO

Date:	19-09-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

Approved WMO Date:	05-12-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	21-02-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	09-03-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	02-06-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	06-06-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	12-07-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-07-2023
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	CTIS2023-507052-69-00
EudraCT	EUCTR2021-004998-32-NL
CCMO	NL82342.028.22