The *Long-term Evaluation of elective neurovascular imAge-Guided and neUrosurgical trEatments (LEAGUE-neuro)* study

Published: 18-02-2022
Last updated: 05-04-2024

To set up a prospective cohort that facilitates evaluation of elective neurovascular treatments and that will serve as a multi-trial platform.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON54079

Source
ToetsingOnline

Brief title
LEAGUE-neuro

Condition

- Central nervous system vascular disorders
- Aneurysms and artery dissections

Synonym
blood vessel disease of the brain, Neurovascular anomalies

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cohort, Neurovascular treatments, Patient-reported outcomes, TwiCs

Outcome measures

Primary outcome

Clinical parameters (e.g. co-morbidity, neurological history, symptoms, imaging parameters, technical and treatment data), clinical endpoints (complication rate, effectiveness, recurrence, technical outcome parameters, survival), and patient reported outcomes (e.g. QOL).

Secondary outcome

N/A

Study description

Background summary

Approximately 3% of the general population harbors a neurovascular anomaly, such as an aneurysm, arteriovenous malformation or dural arteriovenous fistula. These conditions can cause debilitating symptoms, and sometimes carry a high rupture risk which could lead to subarachnoid hemorrhage, a condition with poor prognosis. Therefore, selected cases are treated preventively. The field of neuro-interventional radiology has gained an important role in treatment of neurovascular disease over the past decades next to the conventional neurosurgical approach. Employing a minimally invasive approach through the blood vessels, the techniques used within this field put a lower burden on the patient compared to surgical approaches. At the same time, the neurosurgical approach remains indispensible for more complicated cases. New devices are developed at high pace, and being implemented in clinical practice without evidence for their efficacy from randomized trials. Moreover, But long-term efficacy data and long-term impact on quality of life often remain unknown. We aim to build a neuro-interventional cohort according to the which will serve as a multi-trial facility for interventional treatment studies. The Trials within Cohorts (TwiCs) design, also known as cohort multiple Randomized Controlled Trial design (cmRCT). This will be used both as a prospective registry for

assessment of long-term safety, performance and efficacy of innovative neurovascular treatments, and as a multi trial facility for neurovascular treatment studies. In this way, we can compare outcomes of different types of neurovascular treatments and personalize them for future patients.

Study objective

To set up a prospective cohort that facilitates evaluation of elective neurovascular treatments and that will serve as a multi-trial platform.

Study design

Observational, prospective cohort study, according to the *Trials within Cohorts* (TwiCs) design.

Study burden and risks

No risk expected for patients participating in the study. Filling out the questionnaires is the only burden for the patients participating in this cohort. It will take approximately 15 minutes to fill out the questionnaires each time.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >= 16 years.
- Patients with an intracranial aneurysm, arteriovenous malformation, or dural arteriovenous fistula, referred for elective treatment at the UMC Utrecht.
- Informed consent - at least - for use of routinely collected clinical data.

Exclusion criteria

Mentally incompetent patients

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-05-2022
Enrollment:	750

Type:	Actual

Ethics review

Approved WMO Date:	18-02-2022
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	05-05-2023
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL78362.041.21