Multicentre Randomised trial of Ghrelin in anterior circulation ischemic stroke treated with endovascular thrombectomy. A randomized phase 2 trial

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Ethical review	Approved WMO
Status	Pending
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON51856

Source
ToetsingOnline

Brief title
MR GENTLE

Condition

- Central nervous system vascular disorders

Synonym
ischemic stroke

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Rijnstate Vriendenfonds;eigen vakgroepen

Intervention

Keyword: EVT, Ghrelin, Stroke

Outcome measures

Primary outcome

The primary objective of this study is to assess the effect of ghrelin on the severity of the neurological deficit at seven days after symptom onset in patients with acute ischemic stroke caused by large vessel occlusion of the anterior circulation and treated with EVT.

Secondary outcome

Secondary objectives are assessment of effects of ghrelin on

• functional outcome at 90 days (expressed as the score on the modified Rankin Scale (mRS)),

• neurological deficit at one and three days after symptom onset (expressed as scores on the NIHSS),

• infarct size at day 3±1 (based on MRI measurements),

• blood glucose levels at days 1-7,

• mean blood pressure at days 1-7,

• temperature at days 1-7,

• safety (number of SAEs; mortality).

Study description

Background summary

About half of the patients with acute ischemic stroke treated with endovascular thrombectomy (EVT) remain dependent on the help of others or die in the first 90 days. We hypothesize that treatment with ghrelin, started in the first six hours after stroke onset, improves early recovery and long-term functional outcome in these patients. Ghrelin is a naturally occurring hormone and mildly excitatory neurotransmitter also known as the *hunger hormone.* Treatment with acylated ghrelin consistently improved functional and histological recovery in in vitro and in vivo models of ischemic stroke.

Study objective

The primary objective of this study is to assess the effect of ghrelin on the severity of the neurological deficit at seven days after symptom onset in patients with acute ischemic stroke caused by large vessel occlusion of the anterior circulation and treated with EVT.

Study design

This will be a phase 2 multicenter clinical trial with random treatment allocation, open label treatment and blinded endpoint assessment (PROBE design).

Intervention

Treatment in the intervention group will consist of intravenous acylated ghrelin, 600micrg dissolved in 50cc normal saline, by bolus (short term) infusion in 30 minutes, twice daily, for five days. This treatment will be additional to standard treatment, including intravenous thrombolysis, if indicated.

Study burden and risks

A detailed risk analysis is described in chapter 12.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- a clinical diagnosis of acute ischemic stroke, caused by intracranial large vessel occlusion of the anterior circulation (distal intracranial carotid artery or middle (M1/proximal M2) cerebral artery) confirmed by neuro-imaging (CTA or MRA),
- treatment with EVT, defined as groin puncture in the angio suite,
- CT or MRI ruling out intracranial hemorrhage,
- a pre-EVT score of at least 10 on the NIHSS,
- age of 18 years or older,
- written informed consent.

Exclusion criteria

- pre-stroke disability defined as mRS >=2,
- life expectancy shorter than one year,
- child bearing potential.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Ghrelin
Generic name:	acyl-ghrelin

Ethics review

Approved WMO Date:	03-04-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-10-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-08-2024

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-09-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-09-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2022-001632-28-NL
CCMO	NL81487.091.22