Deferoxamine in Aneurysmal Subarachnoid Hemorrhage trial

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This study has been transitioned to CTIS with ID 2024-514615-10-01 check the CTIS register for the current data. This study investigates the effectivity and the safety of deferoxamine use in patients with aneurysma subarachnoidhemorrhage.

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

Summary

ID

NL-OMON52890

Source
ToetsingOnline

Brief title
DASH

Condition

- Central nervous system vascular disorders
- Vascular therapeutic procedures
- Aneurysms and artery dissections

Synonym
cerebral vasospasm, Delayed cerebral ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Delayed cerebral ischemia, Iron chelator, Subarachnoid hemorrhage

Outcome measures

Primary outcome

Primary endpoint is the occurrence of DCI

Secondary outcome

Secundary endpoint is the total number of patients with drug related adverse

events.

Study description

Background summary

Aneurysmal subarachnoid hemorrhage (SAH) is a form of stroke in which secondary neurological deterioration is an
important cause of mortality and morbidity. These secondary changes, so called delayed cerebral ischemia (DCI), are
caused by lysis of erythrocytes which can react to form iron, an toxic
substance to the brain. lron chelators remove the
excess of iron and are standard care in iron-overloaded patients. Deferoxamine (DFO) an chelator has not been
evaluated in SAH patients.

Study objective

This study has been transitioned to CTIS with ID 2024-514615-10-01 check the CTIS register for the current data.

This study investigates the effectivity and the safety of deferoxamine use in patients with aneurysma subarachnoid
hemorrhage.

Study design

A multicenter pilot open-label trial.

Intervention

Deferoxamine for 3 consecutive days. Patients will receive an intravenous dose of 32 mg/kg/day.

Study burden and risks

Patients with aneurysmal subarachnoid hemorrhage have standardized intensive, daily, laboratory and physical controls as part of the necessary treatment. Additional disadvantage for the patients will be the CT or MR scanning directly post treatment, and the MR scanning after 2 weeks. The risks of CT induced radiation effects is very low. The study will not be be done in patients in bad clinical grade at time of randomization.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• 18-85 years old inclusive,
• Subarachnoid hemorrhage diagnosed by CT on admission,
• No history of possible traumatic origin of subarachnoid hemorrhage,
• Eligible for inclusion within 72 hours of subarachnoid hemorrhage,
• Saccular intracranial aneurysm proven by cerebral angiography or CTA,
• Surgical or endovascular obliteration is successfully performed,
• Able to obtain written informed consent from patient or surrogate,
• Patients in good clinical grade (WFNS 1-3) (GCS 13-15) at time of inclusion.

Exclusion criteria

• Pregnancy, as confirmed by routine urine test on admission,
• Abnormal renal function at time of inclusion (eGFR <60 mL/min/1.73m2)
• Elevated liver function test at time of inclusion (AST > 35 U/L and ALT > 45 U/L.)
• History of liver disease or active liver or renal disease,
• Patients with low ferritine (< 20 µg/L),
• Hypersensitivity to deferoxamine,
• Patient taking medication not recommended for concomitant use with deferoxamine as per the product label (e.g. high dose vit. C medication).
• Patients not able to complete the study follow-up.
• The presence of 4 or more of the following risk modifiers for ARDS prior to enrollment:
o Tachypnea (respiratory rate >30),
o SpO2 <95%,
o Obesity (BMI >30)
o Acidosis (pH <7.35),
o Hypoalbuminemia (albumin <3.5 g/dL),
o Concurrent use of chemotherapy

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-12-2022
Enrollment:	40
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Desferal
Generic name:	Deferoxamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-04-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-01-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-08-2022
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
EU-CTR	CTIS2024-514615-10-01
EudraCT	EUCTR2016-002784-34-NL
CCMO	NL69665.091.19