Deferoxamine in Aneurysmal Subarachnoid Hemorrhage trial

Published: 03-01-2018
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This study investigates the safety and tolerability of deferoxamine use in patients with aneurysma subarachnoid hemorrhage.

Ethical review	Not approved
Status	Will not start
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON45310

Source
ToetsingOnline

Brief title
DASH

Condition

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

Synonym
cerebral spasm, 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

Outcome measures

Primary outcome

Primary endpoint is the occurrence of DCI and total number of patients with

drug related adverse events, especially renal, hepatic or neurologic.

Secondary outcome

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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. Iron 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 investigates the safety and tolerability of deferoxamine use in patients with aneurysma subarachnoid hemorrhage.

Study design

A multicenter pilot study randomizing 40 patients into treatment of deferoxamine or placebo.

Intervention

In the treatment arm : DFO Initial dose: 1000 mg, IM or IV (max.IV rate: 15 mg/kg/hr), maintenance dose: 500 mg, IM or IV, every 4 hours. In the placebo arm at the same timepoints an equivalent volume bolus of NaCl 0.9%.

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

Public
Radboud Universitair Medisch Centrum

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL
Scientific
Radboud Universitair Medisch Centrum

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male or Female,

* 18-85 years old inclusive,
* subarachnoid hemorrhage diagnosed by CT on admission,
* Randomizable within 72 hours of subarachnoid hemorrhage,
* Saccular intracranial aneurysm proven by cerebral angiography or CTA,
* Surgical or endovascular obliteration is performed,
* Able to obtain written informed consent from patient or surrogate.
* Patients in good clinical grade (WFNS 1-3)

Exclusion criteria

* Pregnancy, as confirmed by routine urine test on admission,
* Abnormal renal function at time of randomization (GFR <60 mL/min)
* Elevated liver function test at time of randomization (AST > 45 U/L and ALT > 35 U/L.)
* History of liver disease or active liver disease, Active renal disease,
* 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	03-01-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)
Not approved Date:	30-01-2018
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	EUCTR2016□002784□34-NL
CCMO	NL58448.000.17