Effect of simvastatin on endothelial dysfunction, fibrinolysis, coagulation and inflammation after aneurysmal subarachnoid hemorrhage.

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In patients with aneurysmal subarachnoid hemorrhage simvastatin restores endothelial cell damage, activates fibrinolysis, and improves coagulation and inflammation after the hemorrhage.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28808

Bron
NTR

Verkorte titel
N/A

Aandoening

aneurysmal subarachnoid hemorrhage

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Neurology
Overige ondersteuning: Academic Medical Center (AMC), Department of Neurology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The effects of simvastatin on parameters of fibrinolysis, coagulation, inflammation and endothelial function after SAH;
2. The relation between changes in fibrinolytic activity and endothelial cell damage and activation.

Toelichting onderzoek

Achtergrond van het onderzoek

Recently it has been observed that statins decrease the incidence of cerebral ischemia and vasospasm in patients with aneurysmal subarachnoid hemorrhage. This prospective, randomized, double-blind, placebo-controlled trial is an exploratory study designed to investigate the biological effects of simvastatin in patients with aneurysmal subarachnoid hemorrhage.

Doel van het onderzoek

In patients with aneurysmal subarachnoid hemorrhage simvastatin restores endothelial cell damage, activates fibrinolysis, and improves coagulation and inflammation after the hemorrhage.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients will receive simvastatin 80 mg a day or placebo until day 14 after aneurysmal subarachnoid hemorrhage.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with clinical symptoms and signs of SAH with an aneurysmal bleeding pattern on the initial CT scan. CT scan has to be performed within 48 hours after SAH onset;

2. Patients with a perimesencephalic hemorrhage pattern on the initial CT scan while CTA or conventional angiography has shown an appropriate aneurysm. CTA or angiography has to be performed within 48 hours after SAH onset;

3. If CT scan is negative while there is evidence of bleeding in the cerebrospinal fluid (xanthochromia) and the (CT-) angiography has shown an aneurysm.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Under 18 years of age;

2. A time lapse of more than 48 hours after SAH onset;

3. Patients using aspirin or warfarin;

4. Patients already using statins;

5. Contra-indication for simvastatin (active liver disease, liver transaminase more than three times the normal upper limit, myopathy);

6. Kidney insufficiency;

7. If death appears imminent;

8. Pregnancy or lactation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-2006
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-04-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL610
NTR-old	NTR668
Ander register	: N/A
ISRCTN	ISRCTN45662651

Resultaten

Samenvatting resultaten
N/A