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The addition of embolization of the middle meningeal artery will reduce recurrent surgery rate in symptomatic chronic subdural hematoma patients.

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

Samenvatting

Bron

NTR

Verkorte titel

ELIMINATE

Aandoening

Chronic subdural hematoma

Ondersteuning

Primaire sponsor :	Amsterdam University Medical Centers, AMC.
Overige ondersteuning :	N.a.

Onderzoeksproduct en/of interventie

Geen registraties gevonden.

Uitkomstmaten

Primaire uitkomstmaten

- The difference in reoperation rate between the control group and the intervention group

Toelichting onderzoek

Achtergrond van het onderzoek

Chronic subdural hematoma (cSDH) is a frequent neurosurgical disease, especially in the elderly. Most cSDH patients (75%) require burr hole evacuation in order to alleviate their sometimes life-threatening symptoms. One of the biggest disadvantages of burr hole evacuation is that 10-30% of the patients eventually need recurrent surgery for their cSDH. Embolization of the middle meningeal artery is a new treatment for cSDH of which its efficacy has been investigated in small cohort studies and case series. These studies showed a significant reduction in recurrent surgery rate (<5%). The goal of this study is to investigate whether the addition of peri-operative embolization of the middle meningeal artery to standard treatment (burr hole evacuation), lowers recurrent surgery rate in a randomized controlled trial.

Doel van het onderzoek

The addition of embolization of the middle meningeal artery will reduce recurrent surgery rate in symptomatic chronic subdural hematoma patients.

Onderzoeksopzet

First presentation:
Evaluation of baseline parameters (EMV, mRS, mNIHSS, Barthel-index)

During admission for surgery/embolization:
Complications of embolization

8 weeks after intervention:
Evaluation of hematoma recurrence, reoperation rate, mortality, neurological functioning (mNIHSS, MOCA, GCS) and care and health-related costs (iMCQ and iPCQ).

16 weeks after intervention
Evaluation of hematoma recurrence, reoperation rate, mortality, neurological functioning (mNIHSS, MOCA, GCS) and care and health-related costs (iMCQ and iPCQ).

24 weeks after intervention
Evaluation of hematoma recurrence, reoperation rate, mortality, neurological functioning (mNIHSS, MOCA, GCS), quality of life (SF-36, EQ-5D-5L), performance in activities of daily living (Barthel), modified Rankin Scale and care and health-related costs (iMCQ and iPCQ).

Onderzoeksproduct en/of interventie

Peri-operative embolization of the middle meningeal artery (until 72 hours after burr-hole evacuation).

Contactpersonen

Publiek

Amsterdam UMC
Dagmar Verbaan

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Wetenschappelijk

Amsterdam UMC
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- CT-confirmed diagnosis of cSDH

- Primary surgical treatment based on clinical symptoms (progressive neurological deficits).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Significant contraindication to angiography (eg. allergy for contrast)

- Structural causes for subdural hemorrhage, e.g. arachnoid cysts, cortical vascular malformations and a history of cranial surgery in the previous 365 days

- Inability to obtain informed consent from the patient or legal representative (when the patient has a depressed level of consciousness), including language barrier.

- Monocular blindness on contralateral side of the hematoma

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Gerandomiseerd
Blindering :	Open / niet geblindeerd
Controle :	Geneesmiddel

Deelname

Nederland

Status :	Werving gestart
(Verwachte) startdatum :	15-11-2020
Aantal proefpersonen :	170
Type :	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld :	Nee

Toelichting

N.a.

Ethische beoordeling

Positief advies

Datum :	02-10-2020
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	NL8940
Ander register	METC AMC : ABR: NL71901.018.20

Resultaten

Samenvatting resultaten

N.a.