Investigation of Claret cerebral embolic protection device in preventing cerebral lesions during Transcatheter Aortic Valve Replacement

Gepubliceerd: 14-10-2013 Laatst bijgewerkt: 19-03-2025

The use of the Claret device in TAVI procedures reduces the incidence of ischemic cerebral lesions (detected by DW-MRI)

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

Samenvatting

ID

NL-OMON22229

Bron
Nationaal Trial Register

Verkorte titel
MISTRAL-C

Aandoening

Symptomatic severe Aortic Valve Stenosis (AS)
Transcatheter Aortic Valve
Implantation (TAVI)
Cerebral infarctions (CVA)

Ondersteuning

Primaire sponsor: University Medical center (Erasmus MC)
Overige ondersteuning: fund=initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Brain imaging by MRI and detection of
o Presence of new ischemic lesions
o Number of new ischemic lesions per patient
o Total volume of new ischemic lesions per patient

Toelichting onderzoek

Achtergrond van het onderzoek

The TAVI experience is rapidly mounting worldwide. DW-MRI detects subclinical new ischemic cerebral lesions after TAVI in the majority of cases. Although the immediate clinical impact seems negligible, the implications on the longer term are unknown. These subclinical cerebral lesions may play a role in neurocognitive deterioration. If the use of the Claret device in TAVI procedures may reduce the incidence of these cerebral lesions this may have considerable clinical significance in
the long run. Patients who are participating in this study may potentially have a significant clinical benefit.

Doel van het onderzoek

The use of the Claret device in TAVI procedures reduces the incidence of ischemic cerebral lesions (detected by DW-MRI)

Onderzoeksopzet

study duration for patients is a MRI at 3 days postprocedure, routine follow-up at 30 days, and MRI at 6 month

Onderzoeksproduct en/of interventie

The Claret device is an Embolic Protection Device consisting of two nitinol baskets to be introduced through the right radial artery. One basket is positioned in the brachiocephalic trunk, the other in the left common carotid artery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Patients with severe AS at high operative risk who will undergo planned TAVI

2) Informed consent to participate in the study (i.e. use of Claret device yes or no) and undergo DW -MRI before and after the procedure.

3) Compatible left common carotid artery (>= 5 mm) and brachiocephalic artery (>= 9 mm) diameters without significant stenosis (> 70%) as determined by Multi-Slice Computed Tomography (MSCT) scan

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) No written informed consent

2) Standard exclusion criteria for MRI study

3) Transfemoral access not possible

4) Permanent Pacemaker/AICD in situ before TAVI

5) Planned implantation of a pacemaker implantation after TAVI.

6) Previous stroke with residual neurological symptoms or dementia

7) Significant common carotid artery stenosis (> 70%) by MSCT scan

8) Not native Dutch speaking

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-01-2013
Aantal proefpersonen:	54
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-10-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39581
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4092
NTR-old	NTR4236
CCMO	NL40999.078.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39581

Resultaten

Samenvatting resultaten
N/A