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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22229

Source
Nationaal Trial Register

Brief title
MISTRAL-C

Health condition

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

Sponsors and support

Primary sponsor: University Medical center (Erasmus MC)
Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary endpoint

-) Brain imaging by MRI and detection of
o Number of new ischemic lesions per patient

o Total volume of new ischemic lesions per patient
-) 30-day Neurology endpoint: any new transient or focal neurological deficit as determined by an experienced neurologist excluding the time the patient is under influence of anesthetics.
-) Neurocognitive function testing
-) Device related complications: arterial wall damage (dissection) or thrombo-embolisation in the Claret course.

Study description

Background summary

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.

Study objective

The use of the Claret device in TAVI procedures reduces the incidence of ischemic cerebral

lesions (detected by DW-MRI)

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-01-2013
Enrollment:	54
Type:	Anticipated

Ethics review

Positive opinion
Date: 14-10-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39581
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A