Endovascular covered stent as a treatment of vascular complications after TF-AVI

Published: 10-02-2017
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This study will assess the patient* health status regarding vascular symptoms after TF-AVI procedure together with stent function and the rate of stent fractures

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON45529

Source
ToetsingOnline

Brief title
Covered stent after TF-AVI

Condition

- Cardiac valve disorders
- Vascular injuries

Synonym
access site complication, Vascular complication

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: unrestricted grant via AMR (academic medical research;AMC)

Intervention

Keyword: Covered stent, endovascular, TF-AVI, Vascular complications

Outcome measures

Primary outcome

- Symptoms (on WIQ)

- Stent function (on echo Doppler)

- Stent fracture (on X-ray)

- Mortality and MACE

Secondary outcome

-

Study description

Background summary

In treatment with transfemoral aortic valve implantation (TF-AVI), the new aortic valve is brought to the correct position in the hart via catheter guiding which gets its vascular access in the groin. Vascular complications are common (12-30%) and are caused by the large diameter opening used for the passage of the catheter. Possible treatment for these complications is placement of a covered stent, which is already used in treatment of peripheral artery disease (PAD). From 2013 until today the covered stent is used in 30 patients to treat access-related vascular complications in patients who underwent TF-AVI procedure.

Study objective

This study will assess the patient* health status regarding vascular symptoms after TF-AVI procedure together with stent function and the rate of stent fractures

Study design

Retrospective analyses of a (sub)cohort with repeated measurements

Study burden and risks

No serious risks are expected in this study. The radiation dose of the X-ray of the groin is minimal (0.6 mSv), which is futile considering the age of the patients (median age of 82 years) which already got TF-AVI treatment (with at least ten times the radiation dose of the single X-ray we are going to make.). The burden of this study exists of the need for an extra hospital visit to perform the X-ray and ultrasound. Patients benefit from a closer follow-up. This study could not be conducted in another group of patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patient underwent TF-AVI treatment in the AMC (period 2010-2016);- Patient is treated with endovascular, covered stent in the groin area;- Patient is still alive and able to come to the AMC for a follow-up visit;- Patient gives informed consent.

Exclusion criteria

- Patient is deceased;- Patient refuses or is unable to visit the AMC for the follow-up examination

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	10-02-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
CCMO	NL60455.018.17