MANTA* versus suture-based closure after Transcatheter Aortic Valve Implantation Trial

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To investigate whether the collagen-based MANTA vascular closure device (VCD) is superior to suture-based VCDs in preventing vascular access site complications in patients undergoing transfemoral transcatheter aortic valve replacement.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON48880

Source
ToetsingOnline

Brief title
MASH TAVI

Condition

- Cardiac valve disorders
- Vascular injuries

Synonym
injury of an artery, vascular complications

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: femoral artery, TAVI, Vascular closure device

Outcome measures

Primary outcome

The composite of major vascular complications, and minor vascular complications according to VARC 2 at 30 days.

Secondary outcome

- The individual components of the primary endpoint at 30 days and 1 year: major- and minor vascular complications defined bij VARC 2.
- All-cause death including cardiac death, non-cardiac vascular death, non-cardiovascular death.
- Major or life threatening bleedings according to VARC 2
- Need for transfusions for access site related bleeding/complications
- Vascular closure device failure, defined as: placement of VCD not possible or failure of a closure device to achieve haemostasis at the arteriotomy site leading to alternative treatment (other than manual compression or adjunctive endovascular ballooning)
- Intra-procedural complications at the femoral access site pre-sheath removal including bleeding or swelling around the large bore sheath that may indicate hematoma formation or pseudoaneurysm formation; or peri-procedural angiographic evidence of thrombus formation or significant injury in the aorta or iliac vessels associated with procedural large bore sheath placement and/or sub-optimal anticoagulation.
- Time to haemostasis: elapsed time (minutes) between sheath removal and

observed haemostasis

- Procedure time

- Time to ambulation (TTA)

- Ambulation success

- Technical success

- Treatment success

- Clinically relevant bleeding defined as BARC 2, 3 and 5

- Length of hospital stay

- Pain and discomfort score

Study description

Background summary

The majority of Transcatheter Aortic Valve Implantation (TAVI) procedures is performed through a transfemoral approach. To reach haemostasis several vascular closure devices (VCD) are currently available. Vascular complications are relatively frequent and are often associated with closure device failure.

Study objective

To investigate whether the collagen-based MANTA vascular closure device (VCD) is superior to suture-based VCDs in preventing vascular access site complications in patients undergoing transfemoral transcatheter aortic valve replacement.

Study design

A single-center, investigator-driven, randomized, adaptive open label study

Intervention

One group will undergo arteriotomy closure with the suture-based vascular closure device, the other group will undergo arteriotomy closure with a collagen-based MANTA device

Study burden and risks

There is no extra burden or risk associated with participation as all techniques and inquiries are standard care for our TAVI-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

- Patients undergoing elective transfemoral TAVI for severe aortic valve stenosis with any commercially-available transcatheter heart valve (THV)
- Common femoral artery diameter > 5.0mm (14 - 22F compatible)

Exclusion criteria

- Symptomatic leg ischaemia
- Previous thromboendarterectomy or plastic patch of the common femoral artery
- Previous implantation of a suture-based VCD less than 30 days before, or a plug-based VCD within 6 months
- Unilateral or bilateral lower extremity amputation
- Systemic infection or a local infection at or near the access site
- Allergy to the components any of both devices (i.e. bovine materials or any other device material, including collagen and/or collagen products, polyglycolic or polylactic acid, stainless steel or nickel)
- Active bleeding or bleeding diathesis including thrombocytopenia (platelet count <50,000 cells/UL), thrombasthenia, hemophilia, or von Willebrand disease
- Patients in whom continuous oral anticoagulation therapy cannot be stopped for the peri-procedural period or patients with INR >1.8 at the time of the procedure
- Patient unable to be adequately anti-coagulated for the procedure
- Morbidly obese or cachectic (BMI >40 kg/m2 or <20 kg/m2)
- Anatomical and procedural contraindication for suture-based or Manta closure such as a lack of proper puncture site in the common femoral artery in terms of calcification, size, and atherosclerotic disease
- Absence of computed tomographic data of the access site before the procedure
- Patient cannot adhere to or complete the investigational protocol for any reason including but not limited to geographical residence, psychiatric condition or life threatening disease
- Known pregnancy at time of randomization (in women of childbearing potential a negative pregnancy test is mandatory)
- Participating in trials in which the primary endpoint includes bleeding or vascular complications

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-10-2018
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	MANTA VCD
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-10-2018
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-05-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL66778.078.18