Minimally-invasive upper extremity versus lower extremity for accessory access sites during transcatheter aortic valve implantation

Published: 18-10-2022
Last updated: 30-01-2025

To assess the safety and efficacy of a *minimally-invasive upper extremity* approach (radial artery for pigtail catheter and brachial vein for temporary pacemaker when not pacing over the left ventricular stiff wire OR radial artery and pacing over...

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

Summary

ID

NL-OMON51309

Source
ToetsingOnline

Brief title
TAVI XS

Condition

- Cardiac valve disorders

Synonym
abnormal narrowing of the aortic valve, aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Medtronic B.V.

Intervention

Keyword: Diagnostic access site, Pacemaker access site, Transcatheter Aortic Valve Implantation, Upper extremity approach

Outcome measures

Primary outcome

The primary endpoint is clinically relevant bleeding (BARC type 2, 3 or 5) of

the randomized access site (either diagnostic or pacemaker access site, or

both).

Secondary outcome

Secondary endpoints:

- Time to mobilization after TAVI procedure

- Duration of hospitalization

- Early safety (at 30 days) as defined by VARC-3 criteria

Efficacy endpoints:

- Frequency rate of cross-over to the non-randomized access site (either

diagnostic or pacemaker access site, or both)

- Fluoroscop time and skin-to-skin time

- Failure of the temporary pacemaker

Study description

Background summary

During a transcatheter aortic valve implantation (TAVI) procedure, a temporary

pacemaker wire is inserted via the femoral or jugular vein to perform rapid pacing during pre- or post-dilation or in case of the use of a balloon-expandable valve. Pacing can also assist in proper valve positioning and provides a direct back-up in case of conductance disorders during the procedure. The first 24-48 hours after TAVI, this temporary pacemaker is kept in situ in order to overcome post-procedure conduction disorders.

The preferred access site (nowadays) for this temporary pacemaker is the femoral vein. Given the large diameter of the femoral vein, access site hematomas are common. In addition, as long as this temporary pacemaker is in situ, the patient is not allowed to mobilize in order to prevent dislocation of this pacemaker wire. This potentially leads to delayed mobilization and longer immobility of the patient.

Besides the venous access site for the aforementioned temporary pacemaker, two more access sites are needed for a TAVI procedure: the artery through which the new bioprosthetic aortic valve is placed (i.e. the TAVI access site) and the artery through which the pigtail catheter with contrast agent is placed (i.e. the diagnostic access site). In general, the preferred diagnostic access site is the femoral artery. However, also hematomas around the femoral artery when used as diagnostic access site are common. We hypothesize that the use of the radial artery as diagnostic access site causes less access site hematomas as compared to the femoral artery. The same applies for using the brachial vein instead of the femoral vein as temporary pacemaker access site. In addition, we hypothesize that the use of the brachial vein for the temporary pacemaker facilitates earlier mobilization and leads to a shorter duration of hospitalization when compared to using the femoral vein.

Study objective

To assess the safety and efficacy of a *minimally-invasive upper extremity* approach (radial artery for pigtail catheter and brachial vein for temporary pacemaker when not pacing over the left ventricular stiff wire OR radial artery and pacing over the LV stiff wire versus the standard *lower extremity* approach (femoral artery for pigtail catheter and femoral vein for temporary pacemaker when not pacing over the LV stiff wire) OR femoral artery and pacing over the LV stiff wire.

Study design

This is a prospective, multicenter, randomized trial. All patients undergoing a transfemoral TAVI and who comply with the inclusion and exclusion criteria will be randomized in a 1:1 fashion between *minimally-invasive upper extremity* group (experimental arm) and *lower extremity* group (comparative arm).

Intervention

Eligible patients will be randomized in a 1:1 ratio to either the *minimally-invasive upper extremity* group (i.e. radial artery for pigtail catheter and brachial vein for temporary pacemaker when not pacing over the left ventricular stiff wire OR radial artery and pacing over the LV stiff wire versus the standard *lower extremity* approach (femoral artery for pigtail catheter and femoral vein for temporary pacemaker when not pacing over the LV stiff wire) OR femoral artery and pacing over the LV stiff wire.

Study burden and risks

There is no additional risk for patients associated with study participation, besides the risk of the TAVI procedure itself.

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

1. Patients must be > 18 years old.
2. Written informed consent is obtained from all patients.
3. Planned for transfemoral TAVI procedure.

Exclusion criteria

1. Inability to obtain informed consent.
2. Contra-indication for brachial or femoral vein access (temporary pacemaker access site).
3. Contra-indication for radial or femoral artery access (diagnostic access site).
4. Use of cerebral embolic protection device (CEPD) if this requires an additional (arterial) access site

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:	Completed
Start date (anticipated):	28-11-2022
Enrollment:	238
Type:	Actual

Medical products/devices used

Generic name:	Pacemaker wire

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-10-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL80895.091.22