The Effect of Subclinical Leaflet Thrombosis and Prosthesis Type on Transcatheter Aortic Valve Degeneration

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Primary objectives: 1. To assess the difference in bioprosthetic leaflet 18F-NaF PET activity, as an early marker of transcatheter valve degeneration, between patients with vs. without SCLT at five years after TAVI.2. To assess the difference in...

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

Summary

ID

NL-OMON53711

Source
ToetsingOnline

Brief title
POPular PET TAVI

Condition

- Cardiac valve disorders

Synonym
aortic valve stenosis, narrowing of the aortic valve

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Medtronic,Onderzoeksfonds St. Antonius Ziekenhuis; Medtronic

Intervention

Keyword: Bioprosthetic valve degeneration, Prosthetis type, Subclinical valve thrombosis, TAVI

Outcome measures

Primary outcome

Quantified bioprosthetic micro-calcification activity (18F-NaF uptake)

Subclinical leaflet thrombosis (Hypo Attenuating Leaflet Thickening and Reduced

Leaflet Motion)

Bioprosthetic valve dysfunction

Secondary outcome

Demographics, comorbidities, cardiovascular risk factors and scores, clinical

status and frailty scales, laboratory values, procedural factors, and baseline

and (early) follow-up echocardiography measurements.

Study description

Background summary

Subclinical leaflet thrombosis (SCLT) occurs frequently after transcatheter aortic valve implantation (TAVI) and has been associated with an increased risk of valve dysfunction. A persistent form of SCLT may lead to thrombus calcification and valve degeneration and increase the long-term risk of symptomatic bioprosthetic valve deterioration. Intra-annular in comparison to supra-annular TAVI valves have been associated with a higher risk of SCLT and clinical valve thrombosis. Intra-annular valves may create larger neo-sinuses and flow stagnation zones, which favour local thrombogenicity. Whether different prosthesis types lead to a higher degree of transcatheter valve calcification and degeneration is currently unexplored. Recently, 18F-sodium fluoride (18F-NaF) positron emission tomography (PET) has emerged as a non-invasive modality capable of imaging bioprosthetic micro-calcification activity, which is an early and powerful predictor of valvular dysfunction and eventually valve failure. In the present study, we investigate the differences in quantified bioprosthetic micro-calcification activity with 18F-NaF PET as

early marker of transcatheter valve degeneration between patients with and without SCLT and between patients with intra-annular vs. supra-annular prostheses at five years after TAVI.

Study objective

Primary objectives:
1. To assess the difference in bioprosthetic leaflet 18F-NaF PET activity, as an early marker of transcatheter valve degeneration, between patients with vs. without SCLT at five years after TAVI.
2. To assess the difference in quantified bioprosthetic leaflet 18F-NaF PET activity between patients with intra-annular vs. supra-annular TAVI prostheses at five years after TAVI.

Secondary objectives:
1. To assess the prevalence of SCLT at five years after TAVI.
2. To assess whether SCLT and bioprosthetic leaflet 18F-NaF PET activity are associated with echocardiographic measures of valve dysfunction.

Study design

International, cross-sectional cohort study.

Study burden and risks

Patient burdening consists of one study visit to the hospital, during which a PET-CT scan and a transthoracic echocardiogram will be made.
Risk consists of a radiation dose of 8 mSv with the PET-CT scan. Given their age (>75 years), this will not significantly affect their lifetime risk of cancer.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
o Successful TAVI with Sapien or CoreValve Evolut prosthesis about five years ago
o Able to undergo hybrid 18F-NaF PET-CT scan and transthoracic echocardiography
o Written informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
o Temporary or chronic oral anticoagulation use after TAVI
o Known severe renal insufficiency
o History of iodine contrast allergy
o Known severe paravalvular regurgitation
o History of valve-in-valve procedure
o History of aortic valve re-intervention (including percutaneous paravalvular leak closure)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2023
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT05758662
CCMO	NL82791.100.23