Effects of Transcatheter Aortic Valve Implantation on Left Ventricular Function And Coronary Hemodynamics

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

Summary

ID

NL-OMON39853

Source
ToetsingOnline

Brief title
Effects of TAVI on LVF and coronary hemodynamics

Condition

- Cardiac valve disorders

Synonym
aortic valve narrowing, aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Coronary hemodynamics, Left ventricular function, Trans aortic valve implantation

Outcome measures

Primary outcome

The short and long term change in left ventricular function after transcatheter aortic valve implantation, measured invasively by means of PV-loops and non-invasively with echocardiography and cardiac CT and MRI.

Secondary outcome

The secondary study parameters compared with baseline and, where possible, compared between the TAVI and SAVR are: invasively measured LV systolic and diastolic properties, coronary flow characteristics, LV ejection fraction, LV mass, LV myocardial perfusion, flow properties across the aortic valve, presence/amount of aortic and mitral regurgitation, right ventricular function, cardiac conduction, mortality and morbidity, NYHA functional class and quality of life.

Study description

Background summary

The full, precise effects of transcatheter aortic valve implantation (TAVI) on left ventricular function (LVF) and coronary hemodynamics (CH) have not yet been elucidated. LVF improvement after TAVI and after surgical aortic valve replacement (SAVR) evaluated by echocardiography has been described; however, assessment by cardiac MRI/CT scan immediately after TAVI and on long term has not yet been described. Very limited data is available on CH after TAVI by means of simultaneous intracoronary flow and pressure assessment.
This study is conducted as an observational study in which the effects of transcatheter aortic valve implantation on coronary and left ventricular hemodynamics will be assessed. Our hypothesis states that aortic pressure

gradient reduction after TAVI will improve the left ventricular dynamics immediately after the procedure and continue to improve on the long term. With decreased left ventricle strain and increased perfusion pressure, the coronary hemodynamics is expected to change immediately after valve implantation. A reduction in coronary microvascular resistance is expected on longterm, due to a reduced ventricular hypertrophy. These changes are expected to be comparable to those of SAVR.

Study objective

The main objective of the single center, observational study is to assess the immediate and long term effects of TAVI on LVF and coronary flow by means of pressure volume loops, intracoronary flow assessment, echocardiography and cardiac MRI/CT. Where possible these effects will be compared with those of SAVR

Study design

The study is designed as a single center observational study in which the effects on LVF will be investigated in patients undergoing TAVI.

Study burden and risks

The extent of burden and risks is related to the assessment of PV loops and (ideally simultaneous) coronary flow performed periprocedurally directly prior to and after TAVI. During repeat measurements risks are related to the repeat coronary angiography. The extra radiation exposure is minimal. Uncomplicated assessment of PV loops has been performed in this institute during percutaneous coronary intervention (PCI) in several studies. Also invasive coronary blood flow measurements have been performed in many studies and as part of the regular patient care. The benefit of this study is a better understanding of mechanisms of LVF improvement after TAVI. The knowledge gained by this study can be passed to other interventional cardiologists to improve future treatment with TAVI of high risk patients. Furthermore in case of reduced morbidity and mortality compared to SAVR, the indications for TAVI may increase in high risk patients. Lastly patients may benefit directly from this study because of an improved follow-up.

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

transfemoral transcatheter aortic valve implantation

Exclusion criteria

coronary arteries considered unsuitable by treating interventional cardiologist.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	09-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2014
Application type:	Amendment
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	NL39660.018.12