ATTR amyloidosis in patients undergoing transcatheter aortic valve replacement: from prevalence to hemodynamic consequence.

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Objective: 1. Investigate the prevalence of ATTR in patients undergoing TAVR in the Netherlands.2. To determine whether ATTR influences the effectiveness of TAVR treatment on LV dysfunction.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON55157

Source
ToetsingOnline

Brief title
AMLO-TAVR

Condition

- Other condition
- Cardiac valve disorders

Synonym
Amyloidosis; protein misfolding disease

Health condition

Tevens aandoeningen van hey myocard (amyloidoseophoping).

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: afdeling cardiologie;UMCG,Pfizer

Intervention

Keyword: ATTR, pressure-volume loop, Prevalence, TAVR

Outcome measures

Primary outcome

Main study parameters/endpoints:

1. Prevalence of ATTR, measured by bone scintigraphy, in patients undergoing TAVR.

2. Differences in acute hemodynamic response to TAVR between ATTR and non-ATTR patients.

Secondary outcome

1. To determine the influence (relative contribution) of ATTR to the LV dysfunction in patients with AS undergoing TAVR.

2. To determine whether ATTR influences the effectiveness of TAVR treatment on improvement in Quality of Life.

3. To determine whether ATTR influences survival and future hospitalizations rate after TAVR treatment

4. To determine possible predictors of the presence of ATTR, using echocardiography and biomarkers.

Study description

Background summary

Rationale: Transcatheter aortic valve replacement (TAVR) is currently the treatment of choice in patients with severe aortic valve stenosis (AS). However, not all patients benefit equally from a TAVR. Amyloidosis might be comorbidity which may impact outcome unfavorably. Amyloidosis is known to cause left ventricular (LV) dysfunction and might additionally contribute to symptoms which might not be resolved by TAVR. In the United States of America 16% of TAVR patients were reported to have concomitant transthyretin amyloidosis (ATTR). The prevalence of ATTR in TAVR patients in the Netherlands is unknown as well as its relation with quality of life and outcome.

Study objective

Objective:
1. Investigate the prevalence of ATTR in patients undergoing TAVR in the Netherlands.
2. To determine whether ATTR influences the effectiveness of TAVR treatment on LV dysfunction.

Study design

Study design: Single center, prospective, observational study.

Study burden and risks

In bone scintigraphy the tracer 99mTc-HPD ([technetium-99m] - [3,3-diphosphono-1,2-propanodicarboxylic acid]) is used. It is a minimally invasive procedure, as only the tracer needs to be administered intravenously. A small possibility of an allergic reaction to the tracer is possible. The expected radiation dose from the entire procedure is 4.5 mSv per scan. There is no risk for other people that come in contact with the patient after the scan. The invasive hemodynamic measurements will be obtained with a pressure-volume loop catheter during the TAVR procedure. For this measurement a catheter will be placed in the left ventricle and an extra venous acces sheath will be inserted. These procedures bear minimal additional risk to the patiënts on top op the risk of TAVR procedure.

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

Severe symptomatic aortic valve stenosis

Exclusion criteria

- Unable to undergo scintigraphy

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):	01-10-2020
Enrollment:	340
Type:	Actual

Medical products/devices used

Generic name:	invasive pressure volume loop analysis
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-02-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-05-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL70998.042.19