TAVI versus classic aortic valve replacement (SAVR): real-life comparison using a health insurance dataset

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Study Planned

Administrative details

EU PAS number

EUPAS35801

Study ID

39858

DARWIN EU® study

No

Study countries

☐ Germany

Study status

Planned

Research institutions and networks

Institutions

Institut für Pharmakoökonomie und Arzneimittellogistik (IPAM)

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Institution

Contact details

Study institution contact

Thomas Wilke thomas.wilke@ipam-wismar.de

Study contact

thomas.wilke@ipam-wismar.de

Primary lead investigator

Thomas Wilke

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2020

Actual: 01/06/2020

Study start date
Planned: 30/06/2020

Data analysis start date
Planned: 03/08/2020

Date of final study report
Planned: 30/04/2021

Sources of funding

- Other

More details on funding

IPAM eV. (research organization doing the study)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

This study aims to estimate clinical outcomes of two surgical procedures, surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI), in patients with aortic stenosis in Germany.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Aortic stenosis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

50000

Study design details

Outcomes

The study will measure surgical outcomes based on an analysis of the following clinical events: death, transitory ischemic attack, hemorrhagic stroke, ischemic stroke, stroke, myocardial infarction, arterial embolism, bleeding, periprocedural complications, aortic insufficiency, implantation of a pacemaker, and follow-up aortic valve operations.

Data analysis plan

The study will compare outcomes in two matched cohorts of patients who underwent aortic valve replacement surgery (either TAVI or SAVR) from 01/01/2014-30/09/2018. The two cohorts are composed of: (1) patients who received TAVI and (2) patients who received SAVR. Three main types of analyses will be conducted within the context of this study. The first consists of a descriptive analysis of events in both cohorts with an analysis of differences between TAVI and SAVR subgroups. Secondly, a basic analysis of outcomes (i.e. events and event frequency) will be conducted using propensity score matching. Lastly, a sensitivity analysis will be conducted using a multivariate analysis of unmatched groups to measure the time-to-events (using a Cox proportional hazards model) based on composite endpoints (i.e. death and cardiovascular hospitalizations).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s), other

AOK PLUS sickness fund Germany

Data sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No