Trial Description

Title

TAVI Calculation of Costs Trial

Trial Acronym

TCCT

URL of the trial

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Brief Summary in Lay Language

A health economic analysis of the treatment of aortic stenosis in patients over 75 years is urgently required. It is the legal costs of conventional aortic valve replacement (AVR) and catheter-based aortic valve implantation (TAVI) to identify comparable groups of patients and to analyze in particular the post-procedural course in the light of the emerging post-closure costs.
Noting that up to 60% of elderly patients with symptomatic aortic stenosis surgical treatment is not possible, up to 28% of patients for a percutaneous approach is not appropriate, and taking into account the purely symptomatic approach to conservative treatment with consequently poor prognosis for a holistic, medical and economic assessment, the above observation groups have to be completed with conservative treatment supplement.
The study summarized is a holistic, cost-utility analysis of surgical, and catheter-based drug therapy in high-risk patients with symptomatic aortic valve stenosis over an observation period of two years.

Brief Summary in Scientific Language

The aortic valve stenosis with a prevalence of greater than 3% of those over 75 years already the most common heart valve disease. Due to demographic change is becoming increasingly important is to be expected.
In addition to standard therapy, the conventional-operative aortic valve replacement (AVR), for high-risk patients recently catheter-assisted, minimally invasive alternatives (TAVI) are available.
A health economic analysis is in terms of a cost-benefit analysis in addition to the purely medical evaluation due to the already identified, the predicted market developments and the current situation clearly differing implantation costs (LFS: about 5000-7000 €, TAVI: 35,000 €) is urgently required . Reliable data are missing at this point entirely. It is therefore the legal costs of LFS and TAVI to identify comparable groups of patients and to analyze in particular the post-procedural course in the light of the emerging post-closure costs.
Noting that up to 60% of elderly patients with symptomatic aortic stenosis surgical treatment is not possible, up to 28% of patients for a percutaneous approach is not appropriate, and taking into account the purely symptomatic approach to conservative treatment with consequently poor prognosis for a holistic, medical and economic assessment, the above observation groups have to be completed with conservative treatment supplement.

The study summarized is a holistic, cost-utility analysis of surgical, and catheter-based drug therapy in high-risk patients with symptomatic aortic valve stenosis over an observation period of two years.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00000797**
- Date of Registration in DRKS: **2011/05/09**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **52/11 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **aortic valve stenosis**
- ICD10: **I35.0 - Aortic (valve) stenosis**

Interventions/Observational Groups

- Arm 1: **patients receiving catheter-assisted, minimally invasive aortic valve implantation (TAVI)**
- Arm 2: **patients receiving conventional-operative aortic valve replacement (AVR)**
- Arm 3: **patients receiving conservative treatment**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Health economics**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Total mortality over an observation period of 24 month

Secondary Outcome

Total cost of health services over an observation period of 24 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/04/20**
- Target Sample Size: **300**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
-

Gender: **Both, male and female**

Minimum Age: **75 Years**

- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Age: ≥ 75 years
Significant, symptomatic aortic stenosis is defined by:
- Echocardiographic criteria:
- dpmean aorta> 40 mm Hg or
- vmax aorta:> 4.0 m / s or
- AVA(aortic valve area): <0.8 cm2 (or AVA / BSA <0.5 cm2/m2).
- symptoms:
- NYHA class ≥ II or
- Angina pectoris, CCS class ≥ II or
- Cardiac syncope
Informing the patient or his legal advisor on the study projects. Approval and signature of the consent form. Willingness to Contribute to the study projects.
Commitment to participate in the follow-up visits by the patient.

Exclusion criteria

Acute myocardial infarction within the past month, defined by:
- STEMI or NSTEMI with CK elevation greater than twice the norm, and significant CK-MB fraction and / or significant troponin rise (WHO definition).
Untreated, clinically significant coronary artery disease.
Previous mechanical valve replacement and / or supply any prosthetic heart valve ring
Congenital bicuspid aortic valve or mono-
Non-calcifying aortic valve stenosis
Combined Aortenklappenvitium with aortic valve insufficiency ≥ grade 3
Severe mitral stenosis ≥ grade 3 and / or miter valve insufficiency ≥ grade 3
Sepsis or active endocarditis
Hemodynamic instability, which requires inotropic or mechanical support.
Echocardiographic evidence of intracardiac mass, thrombus or vegetation.
Stroke or TIA within the last 6 months.
Blood value derailment, defined by: Leokozytopenie (cell count <3000/mm3), anemia (HB <9mg/dl), thrombocytopenia (counts <50.000/mm3).
Hemophilia and / or coagulopathy and / or lack of consent to blood transfusions.
Gastro-intestinal bleeding within the last 3 months.
Known intolerance to aspirin (ASA), clopidogrel (Plavix) and / or hypersensitivity to contrast media, which can not be adequately treated.
Need for emergency surgery from any cause.
Limited life expectancy <12 months of non-cardiac cause.

Addresses

■ **Primary Sponsor**

Uniklinik Freiburg, Medzin III, Kardiologie/Angiologie
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■ **Contact for Scientific Queries**

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URL: **[---]***

Sources of Monetary or Material Support

■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Edwards Lifesciences SA
Route de l'Etraz 70
1260 Nyon
Switzerland

Telephone: **[---]***

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Switzerland

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Institutional budget, no external funding (budget of sponsor/PI)**

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E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*
**** This entry means that data is not displayed due to insufficient data privacy clearing.*