Trial Description

Title

German David Registry: Outcomes and risk factors of failure after valve-sparing aortic root replacement

Trial Acronym

German David Registry

URL of the trial

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Brief Summary in Lay Language

The purpose of the proposed study is to identify risk factors of reoperation and heart valve dysfunction after aortic valve repair operations. A prospective multi-center register trial will be performed with five participating centers.

Brief Summary in Scientific Language

The different variants of the David valve-sparing aortic root replacement operation are attractive treatment alternatives to prosthetic aortic valve replacement in selected patients. So far, no multicenter studies on this subject are available, either combining clinical experience and retrospectively avaible clinical outcome data from different aortic surgical centers, nor to prospectively collect clinical and functional outcome data. The exact mechanisms of functional failure of aortic valve reconstruction, including progression of residual aortic regurgitation, new onset aortic valve regurgitation late after the procedure, as well as structural valve deterioration are unknown. The impact of patient-related variables including connective tissue syndromes, bicuspid aortic valve, or geometrical aspects of the aortic root have not been completely understood as of now. In addition the question of selection of specific reconstructive methods on the aortic root as well as of other components of the aortic root including valve cusps and commissures and the influence on functional results have not been studied in detail. The choice of the surgical strategy and early quality assessment of the repair on the basis of structural details of the aortic valve are based on subjective, individual judgement and not on evidence. The impact of a list of preoperative variables including type of bicuspid aortic valve, aortic root geometry, cusp prolapse and others is not known. These uncertainties mandate a first-time multicenter trial to combine the available retrospective outcome data allowing for robust statistical risk factor analysis. A prospectively designed, national multicenter trial will in the future help to identify patient-related, valve-related and surgery-related risk factors of failure of aortic valve sparing surgery. These data will in the future 1. improve patient selection, 2. spare costs caused by reoperations, 3. improve longevity of repair and 4. help to standardize aortic valve-sparing surgery.

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: **DRKS00007872**
- Date of Registration in DRKS: **2015/03/12**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **546/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I35.1 - Aortic (valve) insufficiency**

Interventions/Observational Groups

- Arm 1: **A national multicentre, retrospective, risk factor study is proposed. The study design is nonrandomized and non-blinded. This retrospective study will serve as a basis for the establishment of a prospective clinical registry.**

  The planned retrospective evaluation of follow-up information by combining clinical patient databases from five national aortic surgical centers entails the following time-points:

  1. Direct postoperative valvular follow up including details of valvular characteristics directly after the reconstructive procedure (transesophageal echocardiogram in the operating room)
  2. Early postoperative clinical follow-up which is usually performed within thirty days after the procedure including transthoracic echocardiogram on a regular basis

**3. Mid-term postoperative clinical follow-up which is usually performed up to five years after
the procedure including patient visit, history and transthoracic echocardiogram
4. Long-term postoperative clinical follow-up, which is usually performed ten years after the
procedure including patient visit, history and transthoracic echocardiogram.
Endpoints are new onset aortic regurgitation, progression of any residual aortic regurgitation, incidence of high grade aortic regurgitation, as well as replacement of the aortic valve with a prosthesis or repeat aortic valve repair.
Tested variables include patient-related, repair-related and valve-related characteristics.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**- Reoperation at five and ten years after the procedure
- Aortic valve replacement using a prosthesis five and ten years after the procedure**

Secondary Outcome

Residual aortic valve regurgitation, progression of aortic valve regurgitation, new onset aortic valve regurgitation, incidence of more than mild / severe aortic valve regurgitation. Time points for all mentioned endpoints is at five and ten years after the primary procedure.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Sana Herzchirurgie, Stuttgart**
- University Medical Center **Herz- und thorakale Gefäßchirurgie, Lübeck**
- University Medical Center **Herz- und Gefäßchirurgie, Hamburg**
- University Medical Center **Herzzentrum, Leipzig**
- **Universitäts-Herzzentrum , Freiburg im Breisgau und Bad Krozingen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/06/01**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Patients who underwent one of the variants of the David valve-sparing aortic root replacement procedure as a primary procedure (I-V, intention to treat) with or without the
addition of aortic valve cusp and/or commissure repair
- Aortic root aneurysm AND/OR
- Ascending aortic aneurysm OR
- Acute aortic dissection OR
- Bicuspid aortic valve OR
- Tricuspid aortic valve
- Any degree of aortic valve regurgitation
- Syndromic patients including Marfan Syndrome, Loeys-Dietz Syndrome, Ehlers-Danlos
Syndrome OR
- Non-syndromic patients

Exclusion criteria

- More than mild aortic valve stenosis
- Aortic valve endocarditis
- Reoperation
- Redo-Operation
- Valve not suitable for valve-sparing operation

Addresses

■ **Primary Sponsor**

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Deutsche Herzstiftung e.V.
Vogtstraße 50
60322 Frankfurt am Main
Germany

Telephone: **069 955128-119**

Private sponsorship (foundations, study societies, etc.)

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Fax: **069 955128-313**
E-mail: **popp at herzstiftung.de>**
URL: **www.herzstiftung.de**

Status

- Recruitment Status: **Recruiting planned**
- 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.*