PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Long Term Surveillance of Patients with Right ventricular outflow tract dysfunction treated by surgical conduit implantation versus percutaneous pulmonary valve implantation with Melody Valve

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Long-term surveillance of patients with a narrowing or the lack of heart valve between the right ventricle and the pulmonary artery

Brief Summary in Scientific Language

Long term surveillance of Patients with right ventricular outflow tract dysfunction

Amendement: Subsequent changes; extension and prolongation of patient data collection (formal changes).
Ethics committee aproval 02.04.2019 (229/14S)

Organizational Data

- DRKS-ID: **DRKS00010273**
- Date of Registration in DRKS: **2016/04/14**
- 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.: **229/14 , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **I37.0 - Pulmonary valve stenosis**
- ICD10: **I37.1 - Pulmonary valve insufficiency**

Interventions/Observational Groups

- Arm 1: **Follow up of patients with right ventricular outflow tract dysfunction treated by a percutaneuous pulmonary valve implantation with the melody valve.**
  be observed by
  Echo data: LVOT gradient and mean peak, tricuspid regurgitation, pulmonary regurgitation, Right ventricular function,
  Xray : stent fractures / embolization,
  spiroergometry: efficiency
  MRT and physical examination
- Arm 2: **Follow up of patients with right ventricular outflow tract dysfunction treated by a surgical conduit implantationtreated with operative pulmonary valve replacement as Hancock, homograft, Contegra**

Characteristics

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

Primary Outcome

conduit survival defined as time to explant, re-intervention or re-operation
Observation period at least 2 years

Secondary Outcome

death, endocarditis, structural conduit dysfunction
Observation period at least 2 years
The dysfunction is charged by data Echo

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Deutsches Herzzentrum, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/08/01**
- Target Sample Size: **400**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **5 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

All patients >= 5 years who received either a percutaneous Melody valve or a biological conduit for RVOT dysfunction at the German Heart Centre Munich since 2006
-Patient informed consent / data release form

Exclusion criteria

Patients < 5 years of age

Previous percutaneous valve implantation

No Patient informed consent

Addresses

- **Primary Sponsor**

  Deutsches Herzzentrum München

Primary Sponsor

Deutsches Herzzentrum München
80636 München
Germany

Telephone: **[---]***
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E-mail: **[---]***
URL: **http://www.dhm.mhn.de**

■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

Medtronic GmbH
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Germany

Telephone: **[---]***
Fax: **[---]***
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.*