PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

European Clinical Study for the Application of Regenerative Heart Valves - ESPOIR

Trial Acronym

ESPOIR

URL of the trial

[---]*

Brief Summary in Lay Language

This is a prospective, non-randomized, single-arm, multicentre surveillance study to be conducted in Europe. The Surveillance is designed as a study, where

- ESPOIR PV (pulmonary valve) is prescribed in the usual manner in accordance with the terms of the approval.

- The assignment of the patient to a particular therapeutic strategy is not decided in advance by this Surveillance Protocol but falls within current practice and the prescription of ESPOIR PV is clearly separated from the decision to include the patient in the Surveillance.

- No additional diagnostic or monitoring procedures shall be applied to the patients

- and epidemiological methods shall be used for the analysis of collected data.

Evaluation of decellularized human heart valves for pulmonary heart valve replacement in comparison to current valve substitutes. Safety endpoints include cardiovascular adverse events, time to re-operation, re-intervention and explantation. Efficacy endpoints include freedom from valve dysfunction and hemodynamic performance.

Brief Summary in Scientific Language

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Organizational Data

- DRKS-ID: **DRKS00005936**
- Date of Registration in DRKS: **2014/08/25**
- Date of Registration in Partner Registry or other Primary Registry: **2014/01/10**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02035540 (ClinicalTrials.gov)**
- Sponsor-ID: **Surveillance Protocol 2013-11 (corlife)**
- Other Secondary-ID: **FP7 2007-2013, No. 278453**

Health condition or Problem studied

- Free text: **Heart Valve Disease**

Interventions/Observational Groups

- Arm 1: **Other: Decellularized human valves**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
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Study Type: **Non-interventional**

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Blinding: **[---]***

Who is blinded: **[---]***

Control: **[---]***

Purpose: **[---]***

Assignment: **[---]***

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Amount of SARs (serious adverse reactions); time frame: up to 24 months; Cardiovascular Adverse Reactions; Serious Adverse Reactions, such as infections, immunological reactions, etc.
- Freedom from valve dysfunction; time frame: up to 24 months; Freedom from valve dysfunction leading to re-intervention or explantation at end of the study.

Secondary Outcome

- Blood Parameters; time frame: up to 24 months; Blood Parameters as additional safety data to support presence/absence of Adverse Reactions
- Diameters of ESPOIR PV at end of the study; time frame: after 24 months; Diameters of ESPOIR PV at end of the study in comparison to diameters at implantation
- Time to reoperation; time frame: up to to 24 months; Time to reoperation due to explantation
- Time to death; time frame: up to 24 months; Time to death
- Evaluation of transvalvular gradients; time frame: up to 24 months; valve competence assessed by noninvasive imaging tools such as echocardiography or cardiac magnetic resonance imaging

Countries of recruitment

- BE **Belgium**
- FR **France**
- DE **Germany**
- IT **Italy**
- UK **United Kingdom**

- NL **Netherlands**
- CH **Switzerland**

Locations of Recruitment

- **Hannover Medical School, Hannover**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/08/31**
- Target Sample Size: **200**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Indication for pulmonary valve replacement according to current medical guidelines in heart disease.

- Signed Informed consent of legal guardians or patients, assent of patients.

Exclusion criteria

- The patient has not provided Surveillance informed consent.

- The patient shall not suffer from

- generalized connective tissue disorders (eg, Marfan syndrome), or

- active rheumatic disorders, or

- severe asymmetric calcification of the valve ring.

- The coronary arteries of the patient shall not be in abnormal position or heavily calcified.

- Patients shall not show hypersensitivity against Sodium Dodecyl Sulphate (SDS),
Sodium Desoxycholate (SDC), human collagen (or other elastic fibers) or Benzonase®.

Addresses

- **Primary Sponsor**

  corlife

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  Hannover Medical School
  Axel Haverich, Prof. Dr.

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Public Queries**

  Samir Sarikouch, PD MD

  Telephone: **049511532**
  Fax: **[---]***
  E-mail: **sarikouch.samir at mh-hannover.de**
  URL: **[---]***
- **Collaborator, Other Address**

  Hannover Medical School

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Collaborator, Other Address**

  State University of Medicine and Pharmaceutics, Chisinau, Moldavia

Collaborator, Other Address

State University of Medicine and Pharmaceutics, Chisinau, Moldavia

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

- **Collaborator, Other Address**

Leiden University Medical Center

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

- **Collaborator, Other Address**

Great Ormond Street Hospital for Children NHS Foundation Trust

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

- **Collaborator, Other Address**

University of Padova

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

- **Collaborator, Other Address**

Hôpital Necker-Enfants Malades

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

- **Collaborator, Other Address**

University of Zurich

Collaborator, Other Address

University of Zurich

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

- **Collaborator, Other Address**

  Universitaire Ziekenhuizen Leuven

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

- **Collaborator, Other Address**

  German Society for Tissue Transplantation

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

- **Collaborator, Other Address**

  European Homograft Bank, Belgium

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

- **Collaborator, Other Address**

  Gottfried Wilhelm Leibniz Universität Hannover

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

Sources of Monetary or Material Support

- **[---]***

  Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

[---]*

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

Status

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

Trial Publications, Results and other documents

- Further trial documents **ESPOIR Website**

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 2
- Last processed date by ClinicalTrials.gov: 2014/11/27

** 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.*