European Clinical Study for the Application of Regenerative Heart Valves – ESPOIR (the “Surveillance”)

First published: 27/01/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS5064

Study ID

46898

DARWIN EU® study

No

Study countries

- Belgium
- France
- Germany
- Italy

Moldova, Republic of

Netherlands

Switzerland

United Kingdom

Study description

Both acquired and congenital heart disease can require heart valve replacement. Currently available heart valve substitutes are, however, not ideal as they require anticoagulation, with the risk of bleeding when manufactured from non-organic material, or they degenerate when derived from animals (xenografts) or human tissue donors (homografts), leading to the need for frequent reoperation, especially in children and young adults. An ideal heart valve substitute would have the potential to grow even when implanted in paediatric patients. ESPOIR PV hosts the power to regenerate.The purpose of this investigation is to evaluate decellularized human pulmonary valve, Espoir PV (“ESPOIR PV”) for pulmonary valve replacement rates in comparison to current valve substitutes within a large prospective multicentre surveillance at 8 leading European Centres for Congenital Cardiothoracic Surgery regarding re-operation and re-intervention, hemodynamic performance, growth potential and long term durability.Primary safety endpoints: Rate of cardiovascular adverse reactions, leading to e.g. re-operation, catheter based interventions.Secondary safety data: Collection of medical data to assess the process of tissue vigilance. Collection of medical history to support the presence/absence of adverse events, e.g. infections, arrhythmia.Primary efficacy endpoint: Freedom from valve dysfunction leading to re-intervention or explanation at end of the Surveillance.Key secondary efficacy endpoint: Diameters of ESPOIR PV at end of the Surveillance in comparison to diameters at implantation, transvalvular gradients, valve competence assessed by non-invasive imaging tools such as echocardiography or cardiac magnetic resonance imaging.

Study status

Finalised

Research institutions and networks

Institutions

Cardiothoracic, Transplant, and Vascular Surgery, Hannover Medical School

Germany

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Institution **Educational Institution**

Cardiothoracic, Transplant, and Vascular Surgery, Hannover Medical School

Germany

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Institution **Educational Institution**

Hannover Medical School HTTG Hannover, Germany, Universitatea de Stat de Medicina si Farmacie „Nicolae Testemitanu“ Cisinau, Moldova,

Academisch Ziekenhuis Leiden - Leids Universitair Medisch Centrum Leiden, Netherlands, Great Ormond Street Hospital for Children NHS Trust London, United Kingdom, Università degli studi di Padova, Azienda Ospedaliera di Padova Padua, Italy, Université Paris Descartes Paris, France, Universitaet Zuerich Zürich, Switzerland, Universitair Ziekenhuis Leuven Leuven, Belgium

Contact details

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Study contact

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Primary lead investigator

Axel Haverich

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/12/2011

Study start date
Planned: 15/06/2014

Actual: 05/08/2014

Data analysis start date
Planned: 02/01/2017

Actual: 01/03/2017

Date of final study report
Planned: 31/03/2018

Actual: 31/01/2019

Sources of funding

- EU institutional research programme

More details on funding

European Commission, Project # 278453

Study protocol

20131106 Surveillance Protocol inc. Appendices.pdf (2 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

NCT02035540

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Purpose of this investigation is to evaluate decellularized human pulmonary valve, Espoir PV for pulmonary valve replacement rates in comparison to current valve substitutes within a prospective multicentre surveillance at 8 leading European Centres for Congenital Cardiothoracic Surgery regarding re-operation and re-intervention, hemodynamic performance, growth potential and long-term durability.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single-arm clinical Surveillance

Study drug and medical condition

Medicinal product name, other

decellularized human pulmonary valve, Espoir PV

Population studied

Short description of the study population

Inclusion Criteria

The following inclusion criteria will be used in this Surveillance:

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

2. Informed consent of legal guardians or patients, assent of patients

Exclusion Criteria
1. The patient has not provided Surveillance informed consent.
2. The patient shall not suffer from
a. generalized connective tissue dis-orders (eg, Marfan syndrome), or
b. active rheumatic disorders, or
c. severe asymmetric calcification of the valve ring.
3. The coronary arteries of the patient shall not be in abnormal position or heavily calcified.
4. Patients shall not show hypersensitivity against sodium dodecyl sulphate (SDS), sodium desoxycholate (SDC), human collagen (or other elastic fibers) or Benzonase®

Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Estimated number of subjects

200

Study design details

Outcomes

Safety: Rate of cardiovascular adverse reactions, leading to e.g. re-operation, catheter based interventions.Efficacy: Freedom from valve dysfunction leading

to re-intervention or explanation at end of the Surveillance. Safety: Collection of medical data to assess the process of tissue vigilance. Collection of medical history to support the presence/absence of adverse events, e.g. infections, arrhythmia.Efficacy: Diameters of ESPOIR PV at end of the Surveillance in comparison to diameters at implantation, transvalvular gradients, valve competence assessed by non-invasive imaging tools (echocardiography or MRI).

Data analysis plan

Actuarial analysis according to Kaplan-Meier will be used to show estimated probability of freedom from each AR. Actuarial analysis takes into account both early and late post-operative events. The time from ESPOIR PV implantation to endpoint ESPOIR PV dysfunction that requires either a catheter-based or a surgical procedure will also be calculated according Kaplan and Meier.Patient baseline risk will be statistically compared between all participating centres (Statistics to be provided by the Surveillance Statistician). Chi-square tests will be used to compare categorical risk factors while analysis of variance will be used to compare continuous risk factors. Comparisons will be based on the following demographic and pre-operative variables: age, sex, underlying congenital heart defect, previous (heart valve replacement) surgery, valvular lesion, pre-operative NYHA, concomitant cardiac procedures, and coexisting cardiovascular conditions as well as the size of implanted valves.

Documents

Study results

Abschlußbericht NIS 242 ESPOIR Publikation Boethig 2019.pdf (797.76 KB)
Sarikouch 2022.pdf (2.28 MB)

Study publications

Sarikouch S, Horke A, Tudorache I, Beerbaum P, Westhoff-Bleck M, Boethig D, Rep...

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DoI_Haverich_MHH.pdf (167.3 KB)

Composition of steering group and observers

ESPOIR Ethics and Governance council.pdf (52.45 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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