Aortic Replacement using Individualised Regenerative Allografts: Bridging the Therapeutic Gap - ARISE (the “Surveillance”)

First published: 24/07/2015

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10201

Study ID

35523

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium
- ☐ Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Spain
- [ ] United Kingdom

Study description

The purpose of this investigation is to evaluate decellularized human aortic valve, Arise AV (“ARISE AV”) for aortic valve replacement rates in comparison to current valve substitutes within a large prospective multicentre surveillance at 6 leading European Centres for Cardiothoracic Surgery regarding re-operation and re-intervention, hemodynamic performance, growth potential and long term durability. More qualified centres may be added to supplement the Surveillance cohort. Primary safety endpoints: All-cause mortality, major stroke, life-threatening (or disabling) bleeding, acute kidney injury—stage 3 (including renal replacement therapy), peri-procedural myocardial infarction, major vascular complication, repeat procedure for valve-related dysfunction (surgical or interventional therapy.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 ARISE AV 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

First published: 09/01/2014

Last updated: 20/08/2024

Institution | Educational Institution

Cardiothoracic, Transplant, and Vascular Surgery, Hannover Medical School

Germany

First published: 09/01/2014

Last updated: 20/08/2024

Institution | Educational Institution

Academisch Ziekenhuis Leiden - Leids Universitair Medisch Centrum (LUMC) Leiden, Netherlands, Università degli Studi di Padova (UNIPD) Padova, Italy, University Hospital Clinic de Barcelona Barcelona, Spain, Royal Brompton and Harefield

National Health Service Trust London, UK, Universitair Ziekenhuis Leuven (UZL) Leuven, Belgium, Universitätsklinikum Düsseldorf Klinik für Kardiovaskuläre Chirurgie Düsseldorf, Germany, Allgemeines Krankenhaus der Stadt Wien Vienna, Austria

Contact details

Study institution contact

Samir Sarikouch sarikouch.samir@mh-hannover.de

Study contact

sarikouch.samir@mh-hannover.de

Primary lead investigator

Axel Haverich

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/12/2014

Study start date

Planned: 31/01/2016

Actual: 24/09/2015

Data analysis start date

Planned: 31/01/2019

Date of final study report

Planned: 31/03/2019

Actual: 08/11/2019

Sources of funding

- EU institutional research programme

More details on funding

European Commission Project # 643597 Arise

Study protocol

20150720 ARISESurveillance Protocol2015-01.pdf(435.02 KB)

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

NCT 02527629

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)

Data collection methods:

Primary data collection

Main study objective:

Evaluation of decellularized human heart valves for aortic heart valve replacement in comparison to current valve substitutes within a prospective, non-randomized, single-arm, multi-centre surveillance study to be conducted in in 6 leading european sites and other qualified centres, which may be amended.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

A single-arm clinical surveillance study, Prospective non-randomized study

Study drug and medical condition

Name of medicine, other

decellularized human aortic valve, Arise AV

Population studied

Short description of the study population

Inclusion criteria: Indication for aortic valve replacement according to current medical guidelines. 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 fromgeneralized connective tissue disorders (e.g. Marfan syndrome), or active rheumatic disorders or severe asymmetric calcification of the valve ring. The coronary arteries of the patient shall not bein abnormal position or heavily calcified. Patients shall not showhypersensitivity against Sodium Dodecyl Sulphate, Sodium Desoxycholate, 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

120

Study design details

Outcomes

Primary safety endpoints: Cardiovascular Adverse Reactions, e.g. all-cause mortality, major stroke, life-threatening bleeding, acute kidney injury, peri-procedural myocardial infarction, major vascular complication, repeat procedure for valve-related dysfunctionPrimary efficacy endpoint: Freedom from valve dysfunction leading to re-intervention or explantation at end of the study, Secondary safety endpoints: Blood Parameters as additional safety data to support presence/absence of Adverse Reactions, Time to reoperation, explantation and/or death.Secondary efficacy endpoint: Diameters of ARISE AV at end of the study in comparison to diameters at implantation, transvalvular gradients, valve competence assessed by noninvasive imaging tools

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 ARISE AV implantation to endpoint ARISE AV dysfunction that requires either a catheter-based or a surgical procedure will also be calculated according Kaplan and Meier.

Documents

Study results

ARISE Trial 2020.pdf(908.29 KB)

Study publications

Sarikouch S, Theodoridis K, Hilfiker A, Boethig D, Laufer G, Andreas M, Cebotar…

Sarikouch S, Haverich A, Pepper J, Pomar JL, Hazekamp M, Padalino M, Stellin G,…

Horke A, Bobylev D, Avsar M, Meyns B, Rega F, Hazekamp M et al. Paediatric aort…

Bobylev D, Sarikouch S, Tudorache I, Cvitkovic T, Söylen B, Boethig D, Theodori…

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

20150723 Declaration of Interest Arise Haverich.pdf(346.43 KB)

Composition of steering group and observers

Arise DSMB.pdf(33.23 KB)

Signed code of conduct

2015_0032_Code of Conduct Declaration-SDPP-10201.pdf(98.34 KB)

Signed code of conduct checklist

2015_0032_Code of Conduct Checklist-SDPP_10201.pdf(1.2 MB)

Signed checklist for study protocols

2015_0032_Study Protocol Checklist_SDPP_10201.pdf(626.99 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Case-control surveillance database

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