An Observational Registry on cell-free Allografts (SALAMANDRA)

First published: 14/03/2019

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Study Planned

Administrative details

EU PAS number

EUPAS28002

Study ID

40939

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Germany

Study description

Both, acquired and congenital heart disease can require surgical reconstruction or replacement of cardiac valves and/or arteries. Currently available prosthesis

materials is not ideal. It may require anticoagulation, with the risk of bleeding, if manufactured from non-organic material, or it may degenerate when derived from animals or human tissue donors. The use of Cell-free Allografts, XFA, may reduce the need for frequent reoperation, especially in children and young adults. The purpose of this investigation is to analyse the performance of XFA for cardiovascular reconstruction, such as valve replacement, regarding re-operation and re-intervention, hemodynamic performance and long term durability. This will be an observational registry study of isolated or combined procedures using XFA. The following outcome variables will be analysed: Primary safety endpoints: Rate of cardiovascular Adverse Reactions, Serious Adverse Reactions, such as infections, immunological reactions. Secondary safety data: Post-operative time until re-operation, re-interventions or death. Primary efficacy endpoint: Rate of freedom from XFA-dysfunction leading to re-intervention or explantation. Secondary efficacy endpoint: Macroscopic changes of XFA after implantation, trans-XFA gradients and XFA-competence, as applicable, assessed by non-invasive imaging tools such as echocardiography.

Study status

Planned

Research institutions and networks

Institutions

Hannover Medical School (MHH)

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Cardiothoracic, Transplant, and Vascular Surgery, Hannover Medical School

Germany

First published: 09/01/2014

Last updated: 20/08/2024

Institution | Educational Institution

University Hospital Düsseldorf (UKD)

Germany

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Institution | Hospital/Clinic/Other health care facility

AKH Wien, Österreich

Contact details

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Primary lead investigator

Alexander Horke

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2019

Study start date
Planned: 01/06/2021

Data analysis start date
Planned: 31/12/2030

Date of final study report
Planned: 31/12/2031

Sources of funding

- Other

More details on funding

Hannover Medical School HTTG

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

The purpose of this investigation is to analyse the performance of cell-free allografts for cardiovascular reconstruction, such as valve replacement, regarding re-operation and re-intervention, hemodynamic performance and long term durability.This will be an observational registry study of isolated or combined procedures using cell-free allografts.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Registry study

Study drug and medical condition

Medicinal product name, other

cellfree human pulmonary valveEspoir PV, cellfree human aortic valve Arise AV, cellfree human truncus pulmonalis, Espoir TP, cellfree human Aorta, Arise AT

Population studied

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)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1000

Study design details

Outcomes

Safety:Rate of cardiovascular Adverse Reactions, Serious Adverse Reactions, such as infections, immunological reactions.Efficacy:Rate of freedom from cell-free allograft dysfunction leading to re-intervention or explantation. Safety:Post-operative time until re-operation, re-interventions or deathEfficacy:Macroscopic changes of cell-free allografts after implantation, trans-cell-free allograft gradients and cell-free allograft-competence, as applicable, assessed by non-invasive imaging tools such as echocardiography.

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 postoperative events.The time from cell-free allograft implantation to endpoint dysfunction that requires either a catheter-based or a surgical procedure will be calculated according Kaplan-Meier.Patient baseline risk will be statistically compared between all participating centres. Statistics will be provided by the registry 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 heart defect, previous cardiac surgeries, cardiac lesions, pre-operative NYHA, concomitant cardiac procedures, and coexisting cardiovascular conditions. Also included in the analysis will be the size of implanted cell-free allograft.

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

Declaration of Interests Horke.pdf (1.7 MB)

Composition of steering group and observers

Composition of participating ECs.pdf (39.97 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