

# An Observational Registry on cell-free Allografts (SALAMANDRA)

**First published:** 14/03/2019

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Study

Planned

## Administrative details

### PURI

<https://redirect.ema.europa.eu/resource/40939>

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### EU PAS number

EUPAS28002

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### Study ID

40939

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### DARWIN EU® study

No

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### Study countries

Austria

Germany

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## 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.

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## Study status

Planned

## Research institutions and networks

### Institutions

[Hannover Medical School \(MHH\)](#)

**First published:** 01/02/2024

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**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

UKD Düsseldorf, AKH Wien, Österreich

## Contact details

### Study institution contact

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**Study contact**

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### Primary lead investigator

Alexander Horke

## Study timelines

### **Date when funding contract was signed**

Planned: 01/03/2019

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### **Study start date**

Planned: 01/06/2021

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### **Data analysis start date**

Planned: 31/12/2030

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### **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **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

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## **Non-interventional study design, other**

Registry study

## Study drug and medical condition

### **Name of medicine, 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)

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### **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 death Efficacy: 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.

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### **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

**This study has been awarded the ENCePP seal**



## **Conflicts of interest of investigators**

[Declaration of Interests Horke.pdf](#)(1.7 MB)

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## **Composition of steering group and observers**

[Composition of participating ECs.pdf](#)(39.97 KB)

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# Data sources

## **Data sources (types)**

[Other](#)

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## **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No