European Clinical Study for the Application of Regenerative Heart Valves

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40749

Source
ToetsingOnline

Brief title
ESPOIR

Condition

- Cardiac valve disorders

Synonym
Pulmonary valve disease

Research involving
Human

Sponsors and support

Primary sponsor: corlife oHG
Source(s) of monetary or material Support: EU Commission

Intervention

Keyword: Bioprosthesis, Pulmonary Valve/Surgery, Tissue Scaffolds

Outcome measures

Primary outcome

Primary safety endpoints:

a. Cardiovascular adverse reactions, eg, re-operation, catheter based interventions.

b. Serious adverse reactions, eg, infections, immunological reactions.

Primary efficacy endpoint:

Freedom from valve dysfunction leading to re-intervention or explantation at end of the study.

Secondary outcome

Secondary safety endpoints:

a. Blood parameters as additional safety data to support presence/absence of adverse reactions.

b. Time to reoperation, explantation and/or death.

Secondary efficacy endpoints (i.e. at end of the surveillance in comparison to at implantation):

a. Diameter of the ESPOIR PV.

b. Transvalvular gradients.

c. Valve competence (eg, right ventricular size and function) assessed by noninvasive imaging tools such as echocardiography or cardiac magnetic

resonance imaging.

Study description

Background summary

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 pediatric patients.

Haverich et al. have developed a novel implant for heart valves, which is better tolerated than the known alternatives and which has potential for regeneration. Implants derive from donated, non-cryopreserved, homografts, which are chemically treated to inactivate adhering microorganisms and viruses. The heart valves then are decellularized chemically, so that only connective tissue remains, the heart valve matrix (DHV). DHV is stable and can be stored and shipped. It has been examined in extensive animal studies, including immunological and toxicological analysis, which have shown that the implant is well tolerated and recellularized by the recipient.

The DHV was approved on 22/08/2013 by the German competent authority as the tissue preparation *ESPOIR PV* (PEI.G.11634.01.1) for pulmonary valve replacement.

Meanwhile, more than 80 children and young adults have been treated with DHV for pulmonary valve replacement in Chi*in*u/MD and Hannover/DE and the results have been presented at the Annual Scientific Meeting of the American Heart Association (AHA) in November 2010, published in September 2011 as well as during the ESPOIR Kick-off meeting in January 2012. Although these represent early clinical results only, none of these valves has needed to be explanted due to degeneration or rejection, and immunological follow-up has so far revealed no abnormalities in these patients. Moreover, a near physiological development of valve diameters was observed.

Study objective

The purpose of this investigation is to evaluate the ESPOIR PV 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 rates, hemodynamic performance, growth potential and long term durability.

Study design

This is a prospective, non-randomized, single-arm, multi-centre surveillance study to be conducted in Europe. This study will enrol a minimum of 200 patients implanted with the ESPOIR PV. After valve implantation, patients will be followed and assessed at discharge, 3-, 6-, 12- and, if applicable, 24-months thereafter.

Study burden and risks

Not applicable.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)

Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

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 disorders (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®.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-06-2015
Enrollment:	25

Type:	Actual

Ethics review

Approved WMO Date:	14-01-2015
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02035540
CCMO	NL50870.058.14