Who can participate?

This is a prospective, non-randomized, non-interventional, multi-centre trial to be conducted in Europe. This Study will enrol a minimum of 200 patients implanted with the authorized Study valve.

Study Population
Male and female patients, children and adults, with no specific age limit, requiring replacement for a diseased, damaged, or malfunctioning natural or prosthetic pulmonary valve.

Key Inclusion Criteria
Indication for pulmonary valve replacement according to current medical guidelines in congenital heart disease.

Clinical Endpoints
Safety endpoints include cardiovascular adverse events, time to re-operation, re-intervention and explantation. Efficacy endpoints include freedom from valve dysfunction and hemodynamic performance.

Ethics and Governance Council

The ESPOIR consortium will be assisted and advised by an independent Ethics and Governance Council (EGC), which has been established in addition to the safety and oversight requirements of Good Clinical Practice.

The role of the EGC is to provide independent external supervision and advice regarding the ethical, legal and safety (including data safety) aspects concerning the clinical trial, in particular on all aspects concerning studies in children and donated human tissue.

The EGC will monitor the procedures in place for the clinical trial to ensure the application of the highest ethical standards, thus safeguarding patients' interests and rights.

Web: www.espoir-egc.eu

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MHH Medizinische Hochschule Hannover

E·S·P·O·I·R

European clinical study for the application of regenerative heart valves

About ESPOIR

Beginning in January 2012, the European Union will fund the European Clinical Study for the Application of Regenerative Heart Valves (ESPOIR) trial, coordinated by the Hannover Medical School, Germany, with a grant of 5.2 Million Euros for a period of four years. The aim of ESPOIR is to transplant a heart valve, which is tolerated by the patient's immune system, lasts a lifetime and, for children, even holds the potential to grow with the patient.

The ESPOIR consortium comprises nine leading European pediatric cardiology centres, two tissue banks, the German Society for Tissue Transplantation and the European Homograft bank, who will provide the heart valves, and an innovative SME corlife, who will process the donated valves. Project management for the study will be organized by the Leibniz University Hannover.

Objectives

The main objective of the ESPOIR project is the translation of innovative regenerative therapy, namely the decellularized homograft heart valve (DHV), into widespread clinical use. To achieve this goal, the ESPOIR consortium will:

▪evaluate DHV for pulmonary valve replacement rates in comparison to current heart valve substitutes, such as cryopreserved homografts and xenografts. At least 200 patients are needed for robust statistical analysis regarding re-operation and re-intervention rates, hemodynamic performance, growth potential and long term durability.

▪establish sustained structures for European-wide homograft procurement with special emphasis on small homograft sizes, thereby facilitating increased definitive primary repair in congenital heart defects.

▪disseminate the results of ESPOIR to the scientific community, patient organisations and political stakeholders.

▪implement exploitation structures, e.g. partnership models of the decellularization technique for local, national or European homograft banks.

ESPOIR Partner

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