

EUROPEAN CLINICAL STUDY FOR THE APPLICATION OF REGENERATIVE HEART VALVES - ESPOIR

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Objective

Acquired and congenital heart disease can necessitate heart valve replacement. However, current heart valve substitutes are not considered ideal as they need anticoagulation, bearing the risk of bleeding when manufactured from non-organic material, or they degenerate when they are derived from animals or humans thereby leading to frequent reoperation especially in the young population.

prospective multi-centre trial to include at least 200 patients from 8 leading European Centres for Congenital Heart Surgery, for robust statistical evaluation of DHV in direct comparison to conventional pulmonary valve substitutes.

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Materials and Methods

Decellularised fresh homografts, which have shown promising early results in pulmonary valve replacement in children and young adults, could potentially avoid significant activation of the immune system, as more than 99% of donor DNA is removed during the decellularisation process.

Results

In May 2002, the first human implantation was performed in Chisinau, Moldavia. Since then 91 decellularised only valves have been implanted using the Hannover protocol (66 in the last 4 years). 71 were implanted in the pulmonary position of patients with a mean age of 15.3 ± 10.1 years, a median of 13.5 years, and a range of 0.13- 50.6 years. No explantation for degeneration has been performed so far. Matched comparison (age, type of congenital defect, number of previous operations) to bovine jugular veins and conventional cryopreserved homografts showed superior results not only for freedom from reoperation, but also for the rate of grafts with degenerative signs.

Conclusions and Future Work

These early clinical results have indicated that the decellularised homografts have a potentially superior performance compared to conventional cryopreserved homografts in the pulmonary position. These auspicious results have convinced the European Commission to fund a unique project. Starting in 2013 the ESPOIR consortium will undertake a