

# Clinical study offers new hope for patients with congenital heart disease

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For over fifteen years, Professor Dr. Axel Haverich, Head of the Department of Cardiothoracic, Transplantation and Vascular Surgery, and his team of cardiac surgeons at Hannover Medical School (MHH) have been working on a new method for biological valve replacements which can overcome the limitations of conventional methods and the need for frequent re-operations in the case of congenital heart defects.

The Hannover team has developed a novel approach in which human donor valves undergo a special tissue engineering procedure which modifies them so that only the connective tissue remains (decellularization). Following implantation, the decellularized [heart](#) valve is then repopulated with the patient's own cells, which prevents an immunological rejection of the valve and enables its integration into the patient's body. To date, a total of 100 patients have undergone pulmonary valve replacement using this method. "This new approach has allowed us to achieve results which would not have possible using conventional prostheses", said Professor Haverich.

With Hannover Medical School as lead partner, a clinical study involving eight of Europe's top clinical centres for [congenital heart disease](#) has now been initiated to investigate the long-term results of these innovative [heart valves](#). The ESPOIR study (European clinical study for the application of regenerative heart valves - [www.espoir-clinicaltrial.eu](http://www.espoir-clinicaltrial.eu)) is funded by the European Union with 5.2 million Euro over a four-year period.

This month, the first two patients enrolled in the ESPOIR study successfully underwent surgery at the MHH. One 56-year-old patient received a decellularized donor valve to replace a defective pulmonary valve, 51 years after her first heart operation. The same procedure was carried out for a 7-year-old boy whose right ventricle had become enlarged due to a leaky [pulmonary valve](#) following corrective surgery for a [congenital heart defect](#) with

cyanosis. Both patients recovered well and could be discharged from hospital early with good cardiac function with good reason to hope that they will not need any further heart operations in the future.

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