

First patient in the European Heart Preservation study transplanted

The first patient in XVIVO's European Heart preservation study was transplanted during the month of November. The patent protected Heart Preservation device, developed by Professor Stig Steen and commercialized by XVIVO, uses a novel technique for preservation of the donor heart during transport. Nine European transplant centers will include a total of 202 patients in the trial that forms the basis of a European regulatory approval application and will investigate if the new technology can improve patient outcome and reduce complications after heart transplantation.

XVIVO's European Heart preservation study that now has started will investigate if a novel donor heart preservation technology can improve results after heart transplantation. Lack of donated hearts and the maximum organ transport time is currently limiting the number of patients offered a new heart.

In the approximately 7,500 heart transplants performed in the world each year the absence of blood flow and oxygen during donor heart transport may translate into poor patient outcome after transplantation. XVIVO's novel preservation method includes a machine that supplies the heart with continuous circulation of important substances in an oxygenated solution (patent approved in EU, the USA and Canada) during transport. In animal experiments the function of the donated heart could be better preserved and the preservation time was significantly extended with the device. An earlier safety study published in Nature Communications in June 2020, showed that the use of this heart preservation technology developed by Professor Stig Steen is a safe method for preservation of human hearts.

The XVIVO European Heart Preservation study will include a total of 202 patients and focus on safety and efficacy of XVIVO's new device. Early donor heart dysfunction is often observed after transplantation and can impair short and long term outcome for the patients. The primary objective of the study is to investigate if the novel device may improve results after transplantation.

"We are very excited about this trial really getting started, especially in this difficult year for healthcare workers. We are truly convinced that, more than 50 years after the first heart transplantation, the heart transplantation community needs this game-changing technology", says Professor Filip Rega from the University Hospitals Leuven, Belgium, who is the principal investigator.

"It is encouraging that the European regulatory study for Heart preservation has started since the company believes the device has the potential to enable many more transplants once approved. The pre-clinical and clinical data have so far showed very good results for the XVIVO Heart preservation device", says Dag Andersson XVIVO Perfusion's CEO.

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About Us

XVIVO Perfusion AB is a medical technology company which develops solutions and systems for assessing and preserving organs outside the body and for selecting usable organs and maintaining them in optimal condition pending transplantation. The company is headquartered in Gothenburg, Sweden, and has one office in Lund, Sweden, one office in Groningen, the Netherlands and one office in Denver, USA. The XVIVO share is listed on Nasdaq Stockholm and has the ticker symbol XVIVO. More information can be found on the website www.xvivoperfusion.com.

Attachments

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