



Realheart uses sheep as animal model and performs fitting trials

In February Realheart presented its research plan for 2019. An important part of the plan was to evaluate animal models for the future animal trials. After several studies on calves, the company adds sheep as an alternative, which entails several advantages.

During the meeting with the American authority FDA in April, sheep was accepted as the animal model for Realheart's continued work, which is a strategically important milestone.

Using sheep leads to multiple advantages. For example, the sheep's circulatory system is more similar to humans than the calf's is. Additionally, this alternative leads to a cost saving of about 75% at this development stage, since the calf trials would have had to be performed in the U.S. while the sheep operations can be performed in Europe. There are also advantages with regards to quality, the lab that can now be used has an excellent intensive care unit, which increases the chances for successful long time trials. Additionally, the lab has experience of performing GLP studies for data acquisition preceding clinical trials according to FDA's requirements.

During May, Realheart has performed fitting trials on sheep, and we have thus been able to evaluate and refine the surgical technique. The latest of these trials was performed successfully a couple of days ago.

Realheart TAH has a flexible design which means that it could be adapted to fit the smaller chest volume in sheep. The artificial heart could thereby fit in the body after a couple of attempts and the wound could be closed.

When the pump had been implanted and the heart-lung machine had been disconnected, normal values with regards to blood pressure, oxygen saturation and atrial pressures could be measured. The sheep was breathing by itself and had a normal urine production during the limited time of the trial. Thus, the animal was in a stable condition.

With the successful trials, Realheart now moves to long time trials with the intention to wake up the animal transporting it to the intensive care unit.

"We are very happy with having been able to implant Realheart TAH into the chest of a smaller animal, which not least proves our design flexibility. It is also with great satisfaction that we can note that we are following the development plan and that we have passed this milestone faster than expected", says Azad Najjar, CEO and founder.

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Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart TAH has a unique, patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atriums and two chambers) which provides the opportunity to generate a physiologically adapted blood flow that mimics the body's natural circulation. A unique concept in the medical technology world.