Algisyl-LVR implantable hydrogel (biopolymer) for advanced heart failure

TECHNOLOGY

Algisyl-LVR is an implantable hydrogel (biopolymer) intended to prevent or reverse the progression of advanced heart failure of ischemic and non-ischemic aetiology. It has been developed by LoneStar Heart Inc., and is distributed by Healthlink Europe B.V.

Algisyl-LVR is intended for use in patients who have left ventricular cardiomyopathy (enlarged left ventricle) with reduced ejection fraction and remain symptomatic despite being on optimised evidence-based therapy for heart failure.

The hydrogel is injected directly into specific areas of the dilated left ventricle muscle wall. Once injected, the hydrogel thickens to form gel-like bodies that remain in the heart muscle as permanent implants. These perform the function of a prosthetic scaffold, displacing dilated muscle and reshaping the dilated ventricle. The company claim this reduces the size of the chamber, while reducing left ventricular wall tension and myocardial stress, and improving the heart's pumping efficiency. The company state application of the Algisyl-LVR hydrogel mitigates further dilation and negative remodelling of the left ventricle.

The company state the Algisyl-LVR hydrogel can be administered by a cardiac surgeon via an epicardial injection (10-18 injections) during a single surgical intervention involving an incision into the pleural space of the chest (limited thoracotomy). The company state the procedure is performed on a beating heart and lasts approximately 80 minutes.

The Algisyl-LVR implantable hydrogel received a CE mark in October 2014. The company anticipate launch for private and NHS clinical use in 2015.

The bioabsorbable cardiac matrix (BCM) by Bellerophon Therapeutics is another medical device intended to prevent cardiac remodelling and subsequent congestive heart failure following an acute myocardial infarction. BCM is a sterile solution of sodium alginate and...
calcium gluconate designed to be administered as a liquid during a percutaneous coronary intervention procedure. BCM is currently in an ongoing clinical trial.

POTENTIAL FOR IMPACT

Cardiomyopathy is characterised by dilation of the myocardium (heart muscle), thus reducing its ability to contract. This reduces its pumping capacity and leads to heart failure. Although pharmacotherapy is available for patients with heart failure, some may become unresponsive to it, resulting in progression of the disease and potential repeat hospitalisations. Treatment for patients with advanced stage heart failure also includes support from left ventricular assist devices (LVADs) or a heart transplant, both of which are more invasive options.

Algisyl-LVR is intended to prevent and reverse the progression of moderate to severe heart failure at an earlier stage, by improving the failing heart's structure and function. The company claim studies with the Algisyl-LVR hydrogel have demonstrated improvements in cardiovascular function and exercise capacity. Patients may therefore benefit from an improvement in clinical status and quality of life. Additional benefits for patients include a reduction in adverse clinical events related to worsening heart failure and repeat hospitalisation. The company claim treatment with Algisyl-LVR does not interfere with other heart failure therapies (drugs or devices) and may act in a complementary or synergistic fashion to the regular management of heart failure patients. According to the company, the Algisyl-LVR hydrogel is eventually expected to reduce the need for late-stage heart failure interventions such as LVADs and heart transplants.

The company state a key innovative feature is the use of the inert hydrogel. The company claim costs of administration of the hydrogel are comparable to other implantable devices such as LVADs and cardiac resynchronisation therapy devices. According to the company, administration involves a one-time procedure that does not require a cardiovascular bypass, but will require minimal additional training. The company add that unlike the aforementioned devices, the Algisyl-LVR hydrogel does not require ongoing monitoring and treatment for potential complications. In contrast to active implantable devices that require a power source such as a battery, the company claim the Algisyl-LVR is passive and requires minimal care following its implantation.

If clinical and cost-effectiveness can be demonstrated, the Algisyl-LVR hydrogel may offer an additional option for patients with advanced heart failure.

This technology is predicted to have an impact on the following domain(s) of the NHS Outcomes Framework:

Domain 1  Preventing people from dying prematurely
Domain 2  Enhancing quality of life for people with long-term conditions

For more information on the NHS Outcomes Framework, please go to www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk

EVIDENCE

PUBLISHED PAPERS AND ABSTRACTS

Anker SD, Coats A, Cristian G et al. A multicentre, randomised study assessing the efficacy of left ventricular augmentation with Algisyl-LVR in the treatment of advanced heart failure

Anker SD, Coats A, Cristian G et al. Efficacy of left ventricular augmentation with Algisyl-LVR in the treatment of advanced heart failure patients with ischemic and non-ischemic cardiomyopathy: Results of the AUGMENT-HF multicentre randomised controlled trial.


Lee LC, Zhihong Z, Hinson A et al. Reduction in left ventricular wall stress and improvement in function in failing hearts using Algisyl-LVR. Journal of visualized experiments 2013;74.

Mann DL, Sabbah HN, Hinson A et al. A multicentre, randomised study assessing the efficacy of left ventricular augmentation with Algisyl-LVR in the treatment of advanced heart failure patients with ischemic and non-ischemic cardiomyopathy: Interim results of the AUGMENT-HF study.

http://icvts.oxfordjournals.org/content/19/supp_1/S68.1.short?rss=1

**COMPLETED UNPUBLISHED STUDIES**


**ONGOING STUDIES**


**INFORMATION FROM**

This Alert is based on information from the company and a time-limited internet search.