



Faith's Angels Progress Report

Histotripsy (Therapeutic Ultrasound) for the non-invasive treatment of congenital heart disease

3/5/15

Over the past year, with support from Faith's Angels and other generous contributors, our research team has made significant advances in the development of histotripsy (or focused therapeutic ultrasound) for the treatment of congenital heart diseases such as Hypoplastic Left Heart Syndrome (HLHS). We have designed and created a therapeutic ultrasound delivery device that is customized for a human baby with HLHS. In addition, this therapeutic device has been coupled with a customized imaging transducer, micro-positioning system, and robotic arm to place the integrated imaging and therapy device into position for treatment. In all, within the last year, the first complete and integrated system has been developed for the treatment of patients with HLHS.



With the development of this system and in combination with pre-clinical bench top and live animal testing, with initiated discussions with the Food and Drug Administration (FDA) in regards to applying for approval for an inaugural clinical trial of histotripsy for HLHS. We had a pre-submission meeting with the FDA in Maryland in January 2015. The discussions during and results of the meeting were very promising and positive, suggesting that with further investigation and validation of safety of the device there is a very high chance that approval would be granted for a clinical trial. Over the next few months the team will be working on further validation testing and safety testing of key components of the device. We have also initiated a study to gather more anatomic data from patients with HLHS to further optimize the geometry of our therapeutic device in anticipation of applying for FDA approval within the next year.

In addition to moving full steam on the neonatal HLHS application we will also begin developing a system for fetal, or pre-natal, therapy for children with HLHS or other congenital heart diseases. We have previously generated persuasive data suggesting the histotripsy can be used to treat hearts even before birth, potentially preventing the development of HLHS or decreasing the severity and critical physiology after delivery.

Faith's Angels Inc. is a 501c3 nonprofit organization.

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Over the next year we plan, with support from Faith's Angels, to customize our equipment for human fetal therapy. We will utilize clinical imaging data to guide our design and use 3D printing to develop models or manikins that will allow us to test our device accuracy and effectiveness without having to use as many animal models, which are truly poor models for the human condition. These efforts to advance this technology into fetal therapy for congenital heart disease are currently unfunded. With support from Faith's Angels we hope to generate persuasive data to obtain further support to hopefully develop another clinical tool using therapeutic ultrasound.

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