



## The TRANseptal VERSus retrogradE aortic approach to ablation in the Left Ventricle (TRAVERSE-LV) Trial

### Researchers

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### Lead Alliance Representatives:

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### Background and Study Description:

Fast rhythms arising from the lower chambers of the heart (the ventricles), called “ventricular tachycardia”, or frequent early beats from the lower chambers of the heart, called “premature ventricular contractions” (or “PVCs”) can result in bothersome symptoms and in some cases heart failure and sudden death. One approach to get rid of these abnormal heart rhythms is via a minimally invasive procedure called catheter ablation. When these rhythms are coming from the left ventricle, there are generally two ways to approach the site of interest with an ablation catheter. The most conventional is to use a “retrograde aortic” approach—here the catheter is introduced into an artery in the leg (near the groin), advanced up the largest artery in the body (the aorta), through the aortic valve and into the left ventricle. Importantly, the blood from the aorta feeds the brain and the heart. We recently performed a study where we performed MRIs of the brain before and after these procedures and found that about 60% of all patients undergoing this retrograde aortic approach experienced new lesions (areas of damage) in the brain. An alternative approach would be to advance the catheter through a “transseptal puncture.” In this case, we initially introduce the catheter into a vein (as opposed to an artery) in the leg, cross a very thin membrane between the two atria (upper chambers), enter the left atrium, and then come through the mitral valve to enter the left ventricle. Here, we would not risk disrupting any tissue or creating any debris in the aorta (the blood flow from these veins does not travel to the heart and brain). We know from other studies examining ablations of a different rhythm, atrial fibrillation, which is always performed via a transseptal puncture, that the rates of new lesions in the brain tend to be much lower than what we found in our retrograde aortic procedures, usually around 15-20%. Importantly, there are several reasons why atrial fibrillation ablations would actually be expected to result in *more* new brain lesions (for example, atrial fibrillation itself, unlike PVCs or ventricular tachycardia is known to result in brain lesions, there are more catheter ablations performed when ablating atrial fibrillation compared to ablations for PVCs or ventricular tachycardia)—therefore, it is possible that PVC and ventricular tachycardia ablations via a transseptal may result in rates of new brain lesions substantially *lower* than 15-20%.

Because these brain lesions were not there just before the procedure and were seen only after the procedure (just 1 day after), they are almost certainly due to the introduction of



some material (such as a blood clot, debris from the aorta or aortic valve, or air) during the procedure. However, none of the patients with these new lesions exhibited any problems. Therefore, the real relevance or meaning of these lesions also remains an open question. There is some evidence that, even in the absence of obvious symptoms (such as due to a frank stroke), that subtle negative effects on thinking and more complex tasks requiring brain function may occur. One way to test this carefully and comprehensively is via an examination called “neurocognitive function testing.” We hope to determine whether in fact the damage we are seeing on these brain MRIs leads to a decline in neurocognitive function.

We now seek to perform a study where patients with left ventricular abnormal heart rhythms that are scheduled for a catheter ablation (as determined by their treating physician) will undergo brain MRIs before and after their procedure as well as neurocognitive testing before and after their procedure. They will be randomly assigned to either a transseptal approach or a retrograde aortic approach. We seek to test two hypotheses:

1. That a transseptal puncture will result in less damage to the brain (as detected by brain MRI) than a retrograde aortic approach in patients undergoing catheter ablation in the left ventricle.
2. That a transseptal puncture will result in less neurocognitive function decline than a retrograde aortic approach in patients undergoing catheter ablation in the left ventricle.

## **How this study meets Health eHeart Alliance criteria for sponsorship**

### **1. Scientifically sound cardiovascular-related research**

Please see above. This is relevant to the thousands of patients around the world that undergo this common procedure every year. Of note, successful catheter ablation of the left ventricle has been shown to substantially improve function and quality of life in heart failure patients and can help patients feel remarkably better. We seek to determine how to do this while causing the least harm to patients.

### **2. At least one Health eHeart Alliance member is participating as a patient-leader in a decision-making role and getting compensated for that role**

We will include a patient review board for this project. We have already identified 6 patients with either ventricular tachycardia or PVCs that are interested. Three of them participated in the initial brain MRI study, one recently underwent a successful ablation via a transseptal puncture, and the other two are currently considering whether to undergo ablation or not. All have been encouraged to also enroll in the Health eHeart Study and we will make sure that at least one member (recruiting additional members if needed) is also a Health eHeart Study participant. In



the grant, we will include a budget for patient travel and room and board for an in-person meeting and then reimbursement for twice yearly conference calls.

**3. Accountability reporting on study progress and results back to the Health eHeart Alliance Community and the Steering Committee**

We will be happy to commit to respond to Alliance requests for updates on funding status, naming and connecting the Alliance with a specific person who agrees to serve as an Alliance representative, and plans for results publication and dissemination.

**4. Co-authorship for at least one Alliance patient-leader on final results publication**

We are happy to commit to inviting our Alliance representative(s) to join the writing team as a co-author on the final results publication.

**5. Acknowledgement of the Health eHeart Alliance in the final results paper**

We are also happy to acknowledge the Health eHeart Alliance in the final results paper.

**6. Adequate funding**

We are applying for a PCORI grant to perform a comparative effectiveness study (ie, a comparison of two approaches currently available in clinical practice that have never been prospectively studied in a rigorous fashion). We will budget in patient costs to reimburse for travel and time spent on conference calls. We will directly compensate the patients from this grant.