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We are conducting a clinical research trial that may be of interest to you and your patients. This is a prospective, single-arm non-randomized study to assess the safety and efficacy of fetal embolization of vein of Galen malformations.

Boston Children's Hospital is a national and international referring center for management of vein of Galen malformations with a well-established multidisciplinary consultation pathway at the Maternal Fetal Care Center (MFCC). The trial is being conducted by a multidisciplinary group of specialists from the Boston Children's Hospital Maternal Fetal Care Center, the Boston Children's Cerebrovascular Surgery and Interventions Center, and Brigham and Women's Hospital Maternal Fetal Medicine Group. This clinical group has significant expertise and has pioneered the development of fetal cardiac interventions for severe congenital heart anomalies, a different needle-based intervention. The fetal embolization research intervention will be performed at Brigham and Women's Hospital.

While many vein of Galen patients do very well with conventional treatment after birth, there remains a significant fraction who will develop severe cardiopulmonary symptoms soon after delivery, and this subgroup has a high risk of morbidity and mortality, even with expert care. We have developed a fetal MRI-based screen for identifying this cohort, and the new fetal research intervention is aimed specifically at this group. As opposed to neonatal embolization, we believe that achieving flow diminution through the malformation by partial occlusion of the venous varix *in utero* could potentially preempt development of pulmonary hypertension, and possibly protect both brain and heart from steal-related ischemia. As an additional benefit, morbidity to lower-extremity arteries from femoral catheterization in small infants would be avoided. Moreover, as prenatal treatment would be performed under ultrasound rather than fluoroscopy, procedural exposure to ionizing radiation would also be avoided.

We will enroll 20 subjects in this IRB and FDA-approved research trial. Candidates must have an *in utero* anatomic diagnosis of vein of Galen malformation, must be between 23 weeks and term gestational age, and must have well preserved brain parenchyma. Additional information is available at the clinicaltrials.gov site:

<https://clinicaltrials.gov/ct2/show/NCT04434729?term=orbach&draw=2&rank=1>

If you have a patient who may be interested in this trial, please ask them to contact the Maternal Fetal Care Center at Boston Children's Hospital, at 617-355-6512, or email MFCCreferrals@childrens.harvard.edu. More information about the research intervention and the potential risks and benefits will be provided at that time.