

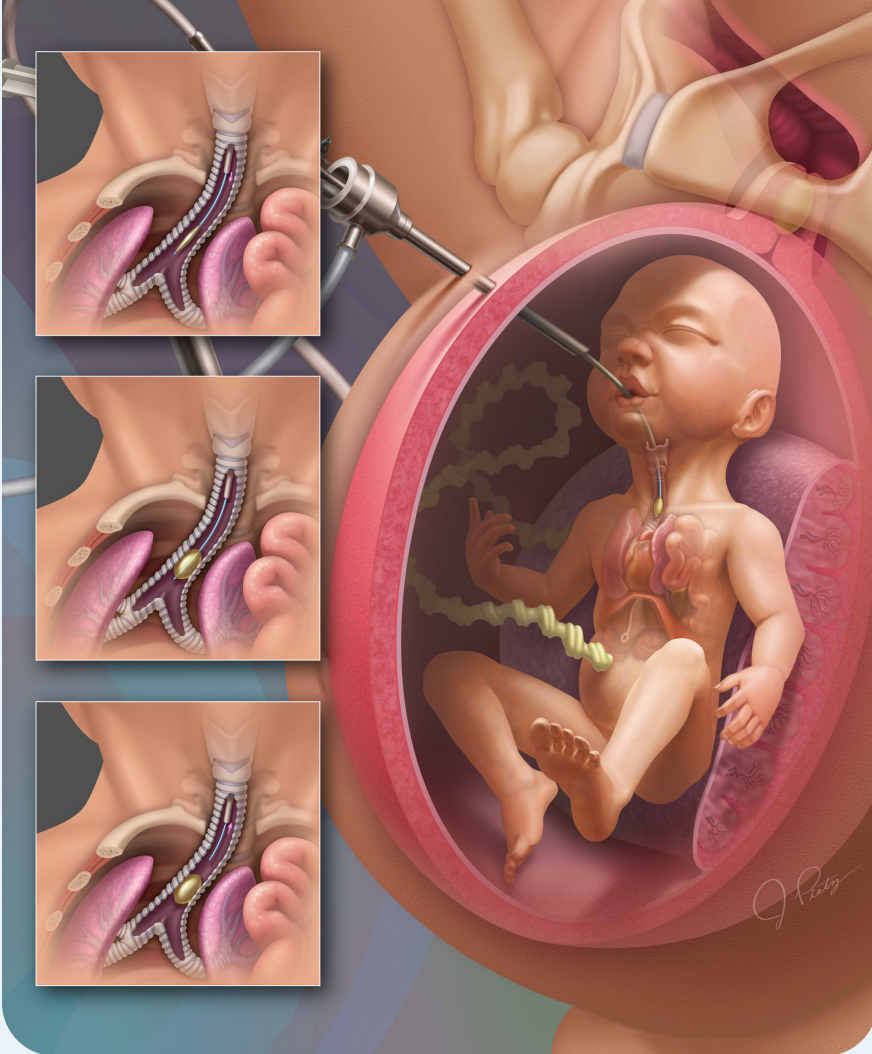
Baylor College of Medicine and
Texas Children's Fetal Center®

Referral Guidelines for Fetal Endotracheal Occlusion (FETO) for Congenital Diaphragmatic Hernia (CDH)

Baylor College of Medicine and Texas Children's Fetal Center are conducting an ongoing trial aimed to evaluate the role of FETO in patients with severe CDH. Our primary outcome is the resolution of pulmonary hypertension by 12 months of age.

 **Texas Children's**
Pavilion for Women

Baylor
College of
Medicine



Below is a list of inclusion and exclusion criteria for the current study:

Inclusion criteria

- Patient is a pregnant woman between 18 and 45 years of age with a singleton pregnancy
- Observed/expected total lung volume equal to or less than 0.32 with more than 21% of liver herniated into the hemithorax as determined by MRI metrics
- Normal fetal echocardiogram or echocardiogram with a minor anomaly (such as a small VSD) that in the opinion of the pediatric cardiologist will not affect postnatal outcomes
- Normal fetal karyotype or microarray
- Patient is healthy enough to have surgery
- Patient and father of the baby provide signed informed consent
- Patient willing to remain in Houston for the duration following the balloon placement until delivery with support person (i.e. spouse, partner or parent)
- Balloon placement would be between 28 0/7 weeks and 31 6/7 weeks gestation as determined by a full evaluation at our center.

Exclusion criteria

- Contraindication to abdominal surgery, fetoscopic surgery or general anesthesia
- Allergy to latex
- Allergy or previous adverse reaction to a study medication specified in this protocol
- Preterm labor, preeclampsia, or uterine anomaly (e.g. large fibroid tumor) in the index pregnancy
- Fetal aneuploidy, known genomic variants, other major fetal anomalies that may impact the fetal/neonatal survival or known syndromic mutation
- Suspicion of major recognized syndrome (e.g. Fryns syndrome) on ultrasound or MRI
- Maternal BMI >40
- High risk for fetal hemophilia



Please call **832-822-2229** to discuss the eligibility of your patient(s) for participation in the trial or to discuss any questions you may have.

To refer a patient, please scan the QR code or visit women.texaschildrens.org/fetalreferral and fill out our online referral form. Patient historical information and medical records may be uploaded online in the form as well. Please be sure to fill out every field in the form, if possible.