

# Safety and Efficacy of FETO in CDH: A Phase III Trial

NCT06884423

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Holly L Hedrick, MD
<b>Enrollment</b>	80 participants

## Key Eligibility Criteria

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### Inclusion (10)

- Pregnant women age 18 years and older
  - Singleton pregnancy
  - Normal fetal karyotype with confirmation by culture results, whole exome sequencing (WES), whole genome sequencing (WGS), or chromosomal microarray with non-pathologic variants. Results by fluorescence in situ hybridization (FISH) will be acceptable if the patient is greater than 26 weeks.
  - Gestational age at enrollment is prior to 29 weeks 6 days
  - Liver is intrathoracic
- ... and 5 more (see full listing online)

### Exclusion (18)

- Patient is less than 18 years of age
  - Multi-fetal pregnancy
  - History of natural rubber latex allergy
  - Preterm labor, cervix shortened (less than 20 mm at enrollment or within 24 hours of FETO balloon insertion procedure) or uterine anomaly strongly predisposing to preterm labor, placenta previa
  - Psychosocial ineligibility, precluding consent:
- ... and 13 more (see full listing online)

## Locations (2 total)

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Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, United States  
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