Fetal Endoscopic Tracheal Occlusion for Congenital Diaphragmatic Hernia

NCT05962346

Status	RECRUITING
Phase	Not Applicable
Sponsor	Mauro H. Schenone
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (9)

- Singleton pregnancy
- Normal fetal karyotype or microarray. Results by fluorescence in situ hybridization (FISH) will be acceptable if the patient is \> 26 weeks
- Isolated severe left CDH with O/E LHR \< 25%)
- Gestation age at enrollment prior to 29 wks plus 6 days.
- Pulmonary hypoplasia with ultrasound O/E LHR \< 25% (measured at 18 0/7 to 29 5/7 weeks) at the time of surgery.

... and 4 more (see full listing online)

Exclusion (14)

- Multi-fetal pregnancy
- History of natural rubber latex allergy
- Preterm labor, cervix shortened (\<20 mm) at enrollment or within 24 hours of FETO balloon insertion procedure) or uterine anomaly strongly predisposing to preterm labor
- Psychosocial ineligibility, precluding consent: inability to reside within 30 minutes of Mayo Clinic, Rochester and inability to comply with the travel for the follow-up requirements of the trial; patient does not have a support person (e.g. spouse, partner, mother) available to stay with the patient for the duration of the pregnancy at Mayo Clinic
- Right sided CDH or bilateral CDH, isolated left sided with O/E LHR \>25% measured at 18 0/7 to 29 6/7 weeks) as determined by ultrasound

... and 9 more (see full listing online)

Locations (1 total)

Mayo Clinic Minnesota, Rochester, Minnesota, United States