

Fetal Endoscopic Tracheal Occlusion (FETO) for Severe Congenital Diaphragmatic Hernia

NCT05461222

Status	RECRUITING
Phase	Not Applicable
Sponsor	Yair Blumenfeld
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (14)

- Maternal Age: 18-50
 - Singleton gestation
 - Gestational age before 29 weeks 6 days
 - Severe left or right-sided CDH: For severe left sided CDH observed-to-expected lung-to-head ratio (o/e LHR) less than 25% between 22 and 29 6/7 weeks' gestation, liver herniation, MRI lung volumes less than 30% expected based on gestational age nomograms. For severe right sided CDH o/e LHR less than 30 % between 22 and 29 6/7 weeks' gestation, liver herniation, MRI lung volumes less than 30% expected based on gestational age nomograms.
 - Normal genetic karyotype or microarray testing by amniocentesis or chorionic villus sampling (CVS)
- ... and 9 more (see full listing online)

Exclusion (13)

- Contraindications to fetal surgery including poorly controlled hypertension, diabetes or other maternal medical condition including hematological disorder
 - High risk for preterm labor and/or delivery based on either significant history of preterm birth, short cervix (measuring \leq 20mm), significant uterine anomaly or other risk factor, incompetent cervix (requiring cerclage)
 - Non-isolated CDH - CDH with additional structural anomalies
 - Significant maternal obesity defined as a body mass index (BMI) greater than 40. BMI is a calculation which includes a person's height and weight
 - History of natural rubber latex allergy
- ... and 8 more (see full listing online)

Locations (1 total)

Lucile Packard Children's Hospital, Stanford, California, United States

<https://clinicaltrials.gov/study/NCT05461222>

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