INPLASY

Fetoscopic tracheal occlusion for left diaphragmatic hernia: a meta-analysis of randomized controlled trials

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202420087

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 February 2024 and was last updated on 21 February 2024.

INTRODUCTION

Review question / Objective P: fetuses with congenital diaphragmatic hernia on the left side. I: fetoscopic tracheal occlusion. C: standard care. O: 6 months postnatal survival, and preterm birth before 37 weeks. T: randomized controlled trials.

Condition being studied Congenital diaphragmatic hernia (CDH) is a complex condition that poses significant challenges in both diagnosis and management.

METHODS

Search strategy ("congenital diaphragmatic hernia" OR ((congenital) AND ("diaphragmatic hernia"))) AND (RCT OR random OR randomized OR randomised OR randomization OR randomly OR "randomized controlled trial").

Participant or population Fetuses diagnosed prenatally with congenital diaphragmatic hernia on the left side.

Intervention Fetoscopic surgery.

Comparator Standard care.

Study designs to be included Only randomized controlled trials.

Eligibility criteria Eligibility criteria: (1) RCTs; (2) that compare FETO; (3) with standard care; (4) in fetuses diagnosed with CDH; (5) exclusively on the left side.

Information sources We will independently search Pubmed, Embase, and Cochrane Central databases covering the period from inception to February 2024.

Main outcome(s) 6 months postnatal survival, and preterm birth before 37 weeks.

Additional outcome(s) Not applicable.

Quality assessment / Risk of bias analysis Included studies will be evaluated through version 2 of the Cochrane Risk of Bias Assessment Tool (ROB-2) for RCTs.

Strategy of data synthesis Our meta-analysis will comprise a random-effects and restricted maximum-likelihood estimators aiming to address potential disparities across the included trials. In addition, computation of risk ratios (RR) for dichotomous outcomes will be performed with the Inverse Variance method.

Subgroup analysis Observed-to-expected lung-to-head ratio < 25% (severe), and ≥ 25% (moderate).

Sensitivity analysis We plan to conduct sensitivity analyses using leave-one-out, Baujat and L'abbé tests to assess our primary outcome of postnatal survival, and we intended to generate a funnel plot for each outcome to explore the possibility of publication bias.

Language restriction None.

Country(ies) involved Brazil, and United States of America.

Keywords fetal surgery; congenital diaphragmatic hernia; fetoscopic surgery.

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