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Efficacy and safety of sildenafil for the prevention and treatment of bronchopulmonary dysplasia in preterm infants: a systematic review and meta-analysis

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ADMINISTRATIVE INFORMATION

Support - No support.

Review stage at the time of initial registration - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 6 November 2026 and was last updated on 6 November 2026.

INTRODUCTION

Review question / Objective To evaluate the efficacy and safety of sildenafil for the prevention and treatment of bronchopulmonary dysplasia (BPD) in preterm infants.
P: Preterm infants
I: Sildenafil (for prevention or treatment of BPD)
C: Placebo or usual care (no sildenafil)
O: Primary outcomes: incidence of BPD, all-cause mortality. Secondary outcomes: adverse events, improvement rate of pulmonary hypertension, improvement rate of clinical manifestations
S: Randomized controlled trials, observational studies and case series.

Condition being studied Bronchopulmonary dysplasia (BPD) is a chronic lung disease of prematurity, which occurs mainly in preterm infants with immature lungs after exposure to mechanical ventilation and oxygen supplementation. It is associated with increased risks of mortality, pulmonary hypertension, and long-term respiratory sequelae.

METHODS

Search strategy Databases: PubMed, Embase, Cochrane Library, Web of Science, ClinicalTrials.gov, SinoMed.
Search terms: (sildenafil) AND (bronchopulmonary dysplasia OR BPD OR BPD-associated pulmonary hypertension OR BPD-PH) AND (preterm infant* OR premature infant*). No language restriction.

Participant or population Preterm infants with immature lungs, regardless of gender or ethnicity. Infants at risk of bronchopulmonary dysplasia (BPD), infants with established BPD, and infants with BPD-associated pulmonary hypertension (BPD-PH) will be included. Infants with major congenital malformations or chromosomal abnormalities will be excluded.

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Intervention Sildenafil, administered for the prevention or treatment of bronchopulmonary dysplasia (BPD) and BPD-associated pulmonary hypertension (BPD-PH) in preterm infants. The dosage, route and duration of sildenafil will be extracted as reported in original studies.

Comparator Comparators include placebo or routine standard care without sildenafil.

Study designs to be included Randomized controlled trials, observational studies and case series.

Eligibility criteria Excluded study types: reviews, editorials, letters, animal studies, duplicate publications. Studies with insufficient data for outcome extraction will also be excluded. There are no restrictions on language or publication year.

Information sources Electronic databases: PubMed, Embase, Cochrane Library, Web of Science, ClinicalTrials.gov, SinoMed. We will contact the original authors for supplementary data if necessary. Grey literature and trial registers will also be searched.

Main outcome(s) 1. Incidence of bronchopulmonary dysplasia (BPD), defined according to original studies, assessed at 36 weeks' postmenstrual age or at discharge.
2. All-cause mortality before hospital discharge.
3. Adverse events related to sildenafil.
4. Improvement rate of BPD-associated pulmonary hypertension (BPD-PH).
5. Improvement rate of clinical manifestations.
Effect measures: Odds ratio (OR) or risk ratio (RR) for comparative studies; single-group proportion for case series.

Quality assessment / Risk of bias analysis The risk of bias of included randomized controlled trials will be assessed using the Cochrane Risk of Bias 2 tool (RoB 2). Observational studies will be evaluated with the ROBINS-I tool.

Strategy of data synthesis For randomized controlled trials and observational studies, pooled odds ratios (OR) or risk ratios (RR) with 95% confidence intervals will be calculated using a random-effects model. Case series will be synthesized by single-group proportion meta-analysis separately and not combined with comparative data. I^2 will be used to assess heterogeneity.

Subgroup analysis No pre-specified subgroup analyses are planned for this review.

Sensitivity analysis Leave-one-out sensitivity analysis will be performed to assess the robustness of pooled estimates. Studies with high risk of bias will also be excluded in an additional sensitivity analysis if appropriate.

Language restriction There will be no language restriction.

Country(ies) involved China.

Keywords sildenafil; bronchopulmonary dysplasia; BPD-associated pulmonary hypertension; preterm infant; retinopathy of prematurity.

Contributions of each author
Author 1 - Biao Su - Conceptualization, study design, registration, manuscript revision and supervision.
Email: white_glaxy@163.com
Author 2 - Yan Xu - Literature screening, data extraction, statistical analysis, risk of bias assessment.
Author 3 - Bin Wang - Literature screening, data extraction, risk of bias assessment.

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