# INPLASY PROTOCOL

To cite: Sun et al. Efficacy and Safety of Xiyanping injection for Acute Bronchitis in Children: A protocol of Systematic Review and Meta-Analysis. Inplasy protocol 202360033. doi: 10.37766/inplasy2023.6.0033

Received: 10 June 2023

Published: 10 June 2023

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Support: 2019XZZX-LG005.

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

Conflicts of interest: None declared.

# Efficacy and Safety of Xiyanping injection for Acute Bronchitis in Children: A protocol of Systematic Review and Meta-Analysis

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Review question / Objective: 2.2.1 Type of study A randomized controlled trial (RCT) comparing XYP INJ versus western medicine for children with AB. 2.2.2 Type of participants Children under 18 years of age diagnosed with AB were included in randomized controlled trials. 2.2.3 Type of intervention. The intervention group received Xiyanping injection, while the control group received Western medicine. 2.2.4 The exclusion criteria The following studies were excluded: Repeated studies, non-randomized controlled trials, self-control trials, medical records reports, reviews, animal experiments. 2.2.5 Outcomes A primary outcome is the effective rate. Secondary outcome included Time to complete resolution of key symptoms(fever, cough, sputum production, pulmonary rales) and adverse reactions.

Condition being studied: XYP is frequently used to treat AB in children in China, but its instructions are rather simple and lack guidance on its clinical application, which reduces its clinical efficacy. Developing more detailed clinical guidelines on the use of XYP in the treatment of AB is urgently needed. Therefore, this means that systemically reviewing studies on the efficacy and safety of Xiyanping injection for children with AB is necessary.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 10 June 2023 and was last updated on 10 June 2023 (registration number INPLASY202360033).

## **INTRODUCTION**

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#### **METHODS**

Search strategy: Our keywords and searching strategy were as follows: Mesh terms and related synonyms was found databases. Keywords and searching strategy were as follows:(( "acute bronchitis" OR "pediatrics" OR "child\*")AND "Xiyanping").

Participant or population: Children under 18 years of age diagnosed with AB were included in randomized controlled trials.

Intervention: The intervention group received Xiyanping injection.

Comparator: While the control group received Western medicine.

Study designs to be included: XA randomized controlled trial (RCT) comparing XYP INJ versus western medicine for children with AB.

Eligibility criteria: A randomized controlled trial (RCT) comparing XYP INJ versus western medicine for children with AB.

Information sources: A literature search was performed until May 2023 using four English databases (PubMed, EMBASE, web of science, and Cochrane Library) and Three Chinese databases (China National Knowledge Infrastructure(CNKI), Wan Fang Database(WanFang), and Weipu Database for Chinese Technical Periodicals(VIP)). The researcher was searched the international clinical trial registration platform and the Chinese clinical trial registration platform of clinical trials until May 2023.

Main outcome(s): A primary outcome is the effective rate. Secondary outcome included Time to complete resolution of key symptoms(fever, cough, sputum production, pulmonary rales) and adverse reactions.

Quality assessment / Risk of bias analysis: The risk of bias was assessed by two investigators, and disagreements were resolved by three investigators. The risk of bias was assessed using the Cochrane Handbook for Systematic Reviews of Interventions (Version 6.3, 2022).

Strategy of data synthesis: Meta-analysis was conducted for the outcomes of the effectiveness rate and time to complete resolution of key symptoms, including fever, cough, sputum production and pulmonary rales using the RevMan Manager 5.3 software (The Cochrane Collaboration, 2012). To summarize the results, the meta-analysis use the randomeffects models to performing. Effects on dichotomic data were measured by means of risk ratios (RRs) and 95% confidence intervals (CIs), the effects on continuous outcomes were measured by the mean differences (MDs) and 95% confidence intervals (CIs). The random-effects models was used to summarize the meta-analysis results.

Subgroup analysis: 1)by age: We will stratify the patients into two groups, mean age ≥6 years and mean age7 days and treatment course ≤7 days.

Sensitivity analysis: It is necessary to exclude studies with high bias risks and to

modify the statistical model in order to perform sensitivity analysis.

Country(ies) involved: China.

**Keywords:** Xiyanping injection ,Acute Bronchitis, Children, protocol ,Systematic Review and Meta-Analysis.

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