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**Support:** **None.**

**Review Stage at time of this submission:** **Formal screening of search results against eligibility criteria.**

**Conflicts of interest:**
**None declared.**

# Efficacy and Safety of Integrated Traditional Chinese and Western Medicine for Infant Bronchiolitis: a systematic review and meta-analysis

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**Review question / Objective:** **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Integrated Traditional Chinese and Western Medicine for infant bronchiolitis.**
**Condition being studied:** **Bronchiolitis is a common respiratory disease in infants, with a high incidence and death rate in severe cases. Acute bronchiolitis is the most common cause of hospitalization in infants. It is a viral lower respiratory infection and every year it is estimated that about 100,000 children are hospitalized due to bronchiolitis in the USA according to relevant reports. It places a great burden on global health resources. In China, the application of Traditional Chinese Medicine in the treatment of infant bronchiolitis is very common, and there are many related studies. However, due to the language barrier, it has not received enough attention in the international community.**

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 April 2021 and was last updated on 11 April 2021 (registration number INPLASY202140062).

## INTRODUCTION

**Review question / Objective:** **The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy and safety of Integrated Traditional Chinese and Western Medicine for infant bronchiolitis.**

**Rationale:** **Traditional Chinese Medicine has a good clinical efficacy on children's respiratory diseases. By systematic review and meta-analysis of a number of clinical trials, this study will further evaluate the efficacy and safety of TCM in the treatment**

of children with bronchiolitis based on big data.

**Condition being studied:** Bronchiolitis is a common respiratory disease in infants, with a high incidence and death rate in severe cases. Acute bronchiolitis is the most common cause of hospitalization in infants.It is a viral lower respiratory infection and every year it is estimated that about 100,000 children are hospitalized due to bronchiolitis in the USA according to relevant reports. It places a great burden on global health resources. In China, the application of Traditional Chinese Medicine in the treatment of infant bronchiolitis is very common, and there are many related studies. However, due to the language barrier, it has not received enough attention in the international community.

## METHODS

**Search strategy:** We searched articles in the seven electronic database including PubMed, EMBASE, Cochrane Library, CNKI (China National Knowledge Infrastructure), WanFang , VIP(Chinese Science and Technology Periodical Database) and SinoMed/CBM (Chinese Biomedical Database). All the English/Chinese publications until February 4, 2021 have been searched without any restriction of countries. We used MeSH terms and the corresponding free words to search. Search terms:"Medicine, Chinese Traditional","Drugs, Chinese Herbal"," Integrative Medicine" ,"Complementary Therapies","Medicine, Traditional"," Medicine, East Asian Traditional"; " Bronchiolitis"; "randomized controlled trial".

**Participant or population:** Inclusion criteria: infants with bronchiolitis (as diagnosed by a clinician, or using any recognized diagnostic criteria). Exclusion criteria: with congenital heart disease, congenital airway dysplasia, chronic lung disease, malnutrition and other serious diseases.

**Intervention:** Inclusion criteria: Integrated Traditional Chinese and Western Medicine treatment (TCM oral therapy in combination with conventional Western Medicine treatment). Exclusion criteria: Chinese Medicine injection, inhalation therapy with Traditional Chinese Medicine.

**Comparator:** Inclusion criteria: conventional Western Medicine treatment according to relevant guidelines for bronchiolitis. Exclusion criteria: combined oral or injection therapy with Chinese patent medicine.

**Study designs to be included:** Clinical randomized controlled trials.

**Eligibility criteria:** (1) Patients: infants with bronchiolitis (as diagnosed by a clinician, or using any recognized diagnostic criteria). (2) Intervention: infants in treatment groups were given TCM oral therapy in combination with conventional Western Medicine treatment similar to the control group. (3)Comparison: infants in the control group were given conventional Western Medicine treatment according to relevant guidelines for bronchiolitis. (4)Outcomes: clinical efficacy endpoint (invalid, effective, markedly effective, cured), hospitalization time, rate of follow-up recurrences and adverse reactions. (5)Study types: randomized controlled trials.

**Information sources:** We searched articles in the seven electronic database including PubMed, EMBASE, Cochrane Library, CNKI (China National Knowledge Infrastructure), WanFang, VIP(Chinese Science and Technology Periodical Database) and SinoMed/CBM (Chinese Biomedical Database).

**Main outcome(s):** The number of clinical efficacy endpoint: invalid, effective, markedly effective, cured.

**Additional outcome(s):** Hospitalization time, rate of recurrences and adverse reactions.

**Data management:** Choose odds ratios for the evaluation of clinical efficacy endpoints, risk difference for the evaluation of hospitalization time, and relative risk for

the rate of recurrences and adverse reactions.

**Quality assessment / Risk of bias analysis:** The Cochrane Collaboration's risk of bias assessment tool will be used to assess the quality of the included studies. Each study will be assessed at low risk, high risk, or unclear risk relating to the following items: sequence generation, allocation concealment, blinding of outcome assessors, incomplete outcome data, selective outcome reporting, and other sources of bias.

**Strategy of data synthesis:** The clinical efficacy evaluation data will be analyzed using Stata. The datas of hospitalization time, number of follow-up recurrences, and number of adverse reactions will be analyzed using Review Manager.The heterogeneity test among multiple studies will be conducted by using a fixed-effect model. If there is heterogeneity, further heterogeneity analysis will be conducted, or a random effect model will be selected according to the situation. Odds Ratios(OR) is used for ordered data, Relative Risks(RR) is used for dichotomous data while mean difference (MD) is adopted for continuous data as effect size, respectively, all of which are demonstrated with effect size and 95% Confidence Intervals (CI). We will use a statistical evaluation of heterogeneity by $\chi 2$ Test(Cochran Q) to assess the heterogeneity in treatment effect within trials, and assess statistical heterogeneity in each pairwise comparison with I2 statistic.

**Subgroup analysis:** We will do subgroup analyses for trials using Chinese Classical Formulae, and compare the effect size (Odds Ratios) of the subgroups to select the most effective formula.

**Sensitivity analysis:** We would perform sensitivity analyses to explore sources of heterogeneity if enough data is available. The Egger's test and funnel plots will be used to detect the potential publication bias.

**Language:** English or Chinese.

**Country(ies) involved:** China.

**Other relevant information:** None.

**Keywords:** Traditional Chinese Medicine; TCM; Drugs, Chinese Herbal; Integrated Traditional Chinese and Western Medicine; Bronchiolitis.

**Dissemination plans:** I intend to publish the review on completion.

**Contributions of each author:**

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