INPLASY PROTOCOL

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None declared.

Clinical efficacy of Yupingfeng Granule in the treatment of recurrent respiratory tract infections in children: A protocol of systematic review and meta-analysis

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Review question / Objective: **This meta-analysis of randomized controlled trials aims to evaluate the efficacy and safety of Yupingfeng Granule for the treatment of recurrent respiratory tract infections in children.**
Condition being studied: **Recurrent respiratory tract infections (RRTIs) are the most common pediatric disease in children, which seriously affects the physical and mental health of children. An immunomodulator is the main drug for the treatment of this disease, which can induce an immunostimulatory response to respiratory pathogens, but the treatment cycle is long and expensive, and the suitable population of children is limited. According to clinical reports, Yupingfeng Granule (one of the Chinese patent medicines, YPFG) is safe and effective in the treatment of recurrent respiratory tract infections in children, but there is no sufficient evidence to prove it. Therefore, we carried out a systematic evaluation.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 March 2022 and was last updated on 27 March 2022 (registration number INPLASY202230150).

INTRODUCTION

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METHODS

Search strategy: Eight databases and clinical trial registries including Cochrane, PubMed, Embase, CBM, CNKI, Wanfang, VIP, China Clinical Trial Registry, and Clinical Trials were searched by computer from the establishment of those until March 26, 2022, with the following keywords: RRTIs, Yupingfeng Granule, and randomized controlled trial. Using the search method of topic words and free words, two researchers independently searched the literature related to the randomized controlled trial of YPFG in the treatment of RRTIs in children. The Keywords and terms for retrieval: "recurrent respiratory infections" OR "Respiratory Tract Infection" OR "Upper Respiratory Tract Infections" AND "Yupingfeng granule" OR "Yupingfeng granules" AND "randomized controlled trial" OR"RCT".

Participant or population: The patients diagnosed as RRTIs were less than 18 years old, regardless of sex, region, race, origin, course of the disease, and so on.

Intervention: The intervention measures of the experimental group were the use of YPFG alone or in combination with western medicine (recommended in the guidelines, such as bacteriolytic products, pidomod), and the conditions of use included non-infectious period and infective period.

Comparator: The intervention in the control group could be placebo or blank control or western medicine (such as bacteriolytic products, pidomod), and routine treatment could be used during respiratory tract infection.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Inclusion criteria:Study type. Randomized controlled trial.Participants. The patients diagnosed as RRTIs were less than 18 years old, regardless of sex, region, race, origin, course of the disease, and so on.Intervention measures. The intervention measures of the experimental group were the use of YPFG alone or in combination with western medicine (recommended in the guidelines, such as bacteriolytic products, pidomod), and the conditions of use included non-infectious period and infective period; the intervention in the control group could be placebo or blank control or western medicine (such as bacteriolytic products, pidomod), and routine treatment could be used during respiratory tract infection.Exclusion criteria:(1) The subjects were more than 14 years old or complicated with other diseases; (2) the intervention measures of the test group were the use of YPFG combined with other proprietary Chinese medicines, or the intervention measures of the control group were proprietary Chinese medicine, Chinese herbal medicine or non-drug therapy (such as acupuncture, massage, etc.); (3) repeated publication (retaining the literature published earlier) and the full text could not be obtained. (4) literature with obvious errors in trial design or statistical methods and lack of data, and (5) non-clinical randomized controlled trials, such as animal experiments, case reports, experience, theoretical review, mechanism research, and so on.

Information sources: Computer searched 8 databases and clinical trial registries, including Cochrane, PubMed, Embase, CBM, CNKI, Wanfang, VIP, China Clinical Trial Registry, and Clinical Trials. If necessary, we will contact the original researchers as much as possible.

Main outcome(s): The main efficacy indicators include the number of respiratory infections or the disease efficacy based on the number of infections,

TCM syndrome efficacy, or clinical symptom scores.

Quality assessment / Risk of bias analysis: The Cochrane bias risk assessment tool was used to evaluate the quality of the included randomized controlled trials from the following six factors: randomized methods, allocation hiding, blind implementation, data integrity, selective reporting of research results, and other biased sources risks. Each bias risk is assessed at three levels: low risk, high risk, and uncertainty.

Strategy of data synthesis: The RevMan5.3 software (The Cochrane Collaboration, Software Update, Oxford, UK) is used to integrate and analyze the research data of the outcome indicators of the same data category. Continuous variables are expressed by mean difference and standardized mean difference, two-classified variables are expressed by risk ratio, and all data are marked with a 95% confidence interval. Q test and I2 test were used to evaluate the heterogeneity between the studies. If P > 0.1 or I2 < 50%, it indicates that there is no significant heterogeneity, and the fixed effect model is used for data analysis. If P < 0.1 or I2 > 50%, indicating significant heterogeneity, the random effect model was used to analyze the data.

Subgroup analysis: We will conduct a subgroup analysis of the data according to the baseline characteristics included in the study, such as age, course of the disease, intervention, treatment time, and so on, to clarify the efficacy and safety of YPFG in the treatment of RRTIs in children.

Sensitivity analysis: Sensitivity analysis was used to exclude the results one by one or to conduct subgroup analysis to evaluate the impact of the inclusion of the study on the results. When the test level is P 75%, or P < 0.05), it is not suitable for Meta-analysis, and the relevant evidence will be summarized using systematic literature review methods.

Country(ies) involved: China.

Keywords: Recurrent respiratory tract infection in children; meta-analysis; randomized controlled trials; Yupingfeng Granule.

Contributions of each author:

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