INPLASY PROTOCOL

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None declared.

Traditional Chinese medicine for the treatment of pediatric adenoid hypertrophy: A protocol for Systematic Review and Meta-Analysis

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Review question / Objective: **In order to verify effectiveness and safety of traditional Chinese medicine in the treatment of pediatric adenoid hypertrophy.**
Condition being studied: **Pediatric adenoid hypertrophy. A total of 135 potential literatures were selected after extensive browsing and collection. 73 studies remained after duplicates removed. And we excluded 34 literatures that did not meet the research objects by screening the title and abstract of the literature in detail. Immediately after that, we deleted 39 literatures based on the inclusion criteria, and finally, we screened out 11 studies that met the inclusion criteria.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 February 2022 and was last updated on 24 February 2022 (registration number INPLASY202220104).

INTRODUCTION

Review question / Objective: **In order to verify effectiveness and safety of traditional Chinese medicine in the treatment of pediatric adenoid hypertrophy.**

Rationale: **Revman 5.4.1 software provided by the Cochrane Collaboration Network was used for statistical processing. The level of meta-analysis was set as α=0.05. The funnel plot was used to evaluate publication bias, and stata was used to test it. The Mantel-Haenszel method was used for binary variable data, odds ratio (OR) was used as effect index, inverse variance method was used for continuous variable**

data, mean difference (MD) was used as effect index if the same measurement unit was used, and standardized mean difference (SMD) was used as effect index if different. Results point estimates and 95% CI were given. The heterogeneity among the included research results was analyzed by X test (the test level was $\alpha = 0.1$), and the size of heterogeneity was quantitatively judged by combining I2 at the same time. If there was statistical significance between the groups, the random effect model was used for analysis, and if there was no statistical significance, the fixed response model was used. If there is statistical heterogeneity among the research results, the source of heterogeneity is further analyzed, and subgroup analysis is conducted according to the differences in methodology or methods of defining outcome and measurement.

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METHODS

Search strategy: Pubmed：Search: (randomized controlled trial[Publication Type] OR randomized[Title/Abstract] OR placebo[Title/Abstract]) AND ((("Adenoids"[Mesh]) OR (((((Adenoid[Title/Abstract]) OR (Pharyngeal Tonsils[Title/Abstract])) OR (Tonsil, Pharyngeal[Title/Abstract])) OR (Pharyngeal Tonsil[Title/Abstract])) OR (Tonsils, Pharyngeal[Title/Abstract])))) AND (((((((Herbal Drugs[Title/Abstract])) OR (Herbal Drugs, Chinese[Title/Abstract])) OR (Plant Extracts, Chinese[Title/Abstract])) OR (Chinese Plant Extracts[Title/Abstract])) OR (Extracts, Chinese Plant[Title/Abstract]))) OR ("Drugs, Chinese Herbal"[Mesh]))).

Participant or population: Type of patients: the children patients were diagnosed with adenoid hypertrophy diagnosed, regardless of race, nationality, gender, or course of disease.

Intervention: Types of intervention: the experimental group was treated with Traditional Chinese Medicine

Comparator: The control group was treated with conventional western medicine

Study designs to be included: Clinical randomized controlled trial.

Eligibility criteria: (1) No Chinese and English literature; (2) the research objects include adult patients; (3) the cases are less than 20; (3) the exact TCM and TCM theory are not explained in the literature; (4) the conference summary is rare; (5) the original data is insufficient, the data is missing, and the contact with the actors is not successful; (6) the control group uses TCM related therapy.

Information sources: We selected all RCT of Traditional Chinese Medicine for the treatment of pediatric adenoid hypertrophy . After extensive searches on various websites from their establishment to September 1, 2022, including EMBASE, PubMed, the China Science and Technology Journal Database (VIP), the Chinese Biomedical Literature Database (CBM),the Cochrane Library, the China National Knowledge Infrastructure (CNKI), and the WanFang databases, target literatures were picked out.Manual searches would also be performed to track necessary references on related literature. Two independent researchers(MengHui Liu and YanChao Zhang) conducted extensive screening and extracted target-related data from them for classification and integration. The extracted data included the first author, publication year, baseline characteristics, intervention, outcome indicators, and adverse events. In the process of screening, if we encounter

difficulties that are difficult to resolve, we would to discuss and decide in detail with the third researcher(LiXin Li).

Main outcome(s): Types of outcome measures: the primary outcomess included the effective rate.

Additional outcome(s): 1.Snoring score; 2. the volume of adenoid relative to posterior nostril.

Data management: We performed the meta-analyses with the help of RevMan 5.4.1 and stata 12.0 software. Among them, odds ratio(OR) was used to evaluate binary variables, and mean difference (MD) was adopted to evaluate continuous variables. If it was less than 0.5, there was statistically significant, and vice versa. Heterogeneity was adopted to evaluate the effect, if P>0.1 or I2<50%, the result was considered to be non-heterogeneity, the fixed effects model was adopted, otherwise, the random effects model was adopted. Finally, sensitivity analysis would be conducted on each indicator to evaluate the stability, and the Egger test would be performed to test potential publication bias. Similarly, P<0.05 would be considered meaningful.

Quality assessment / Risk of bias analysis: Based on the Cochrane Systematic Review Manual RCT bias risk assessment tool, we completed the risk assessment of the included studies. The contents include the following: (1)random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias.

Strategy of data synthesis: The following were the search keywords and terms we used:(randomized controlled trial[Publication Type] OR randomized[Title/Abstract] OR placebo[Title/Abstract]) AND ((("Adenoids"[Mesh]) OR (((((Adenoid[Title/Abstract]) OR (Pharyngeal Tonsils[Title/Abstract])) OR (Tonsil, Pharyngeal[Title/Abstract])) OR (Pharyngeal Tonsil[Title/Abstract])) OR (Tonsils, Pharyngeal[Title/Abstract]))) AND (((((((Herbal Drugs[Title/Abstract])) OR (Herbal Drugs, Chinese[Title/Abstract])) OR (Plant Extracts, Chinese[Title/Abstract])) OR (Chinese Plant Extracts[Title/Abstract])) OR (Extracts, Chinese Plant[Title/Abstract]))) OR ("Drugs, Chinese Herbal"[Mesh]))).

Subgroup analysis: Subgroup analysis was carried out according to the pre-defined results and differences in measurement methods.

Sensitivity analysis: If the combined studies may have substantial heterogeneity, sensitivity analysis is used.

Language: English.

Country(ies) involved: China; The US.

Keywords: traditional Chinese medicine; adenoid hypertrophy; Meta-analysis.

Contributions of each author:

Author 1 - Menghui Liu - The author drafted the manuscript.
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