INPLASY PROTOCOL

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

Conflicts of interest:
No.

Nasal nebulization inhalation of budesonide for chronic rhinosinusitis with nasal polyps: A protocol for systematic review and meta-analysis

Zheng, PJ[1]; Zhang, YY[2]; Zhang, SH[3]; Liu, GF[4]; Wang, JS[5].

Review question / Objective: **Can nasal nebulization inhalation of budesonide (NNIB) effectively treat chronic rhinosinusitis and nasal polyps (CRNP)?**
Condition being studied: **Chronic rhinosinusitis; nasal polyps; nasal nebulization inhalation; budesonide.**
Information sources: **Studies will be identified by searching the following electronic databases from inception to the March 1, 2019: Cochrane Library, PubMed, EMBASE, Web of Science, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database and China National Knowledge Infrastructure. No restrictions of language and publication status will be imposed in this study. The sample of search strategy for Cochrane Library will be made. We will also adapt similar search strategies to the other electronic databases. Additionally, this study will also search any relevant conference proceedings, dissertations, sources of clinical trial registry, and reference lists of associated reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2020 and was last updated on 17 April 2020 (registration number INPLASY202040108).

INTRODUCTION

Review question / Objective: **Can nasal nebulization inhalation of budesonide (NNIB) effectively treat chronic rhinosinusitis and nasal polyps (CRNP)?**

Condition being studied: **Chronic rhinosinusitis; nasal polyps; nasal nebulization inhalation; budesonide.**

METHODS

Participant or population: All patients who were diagnosed as NNIB will be included regardless their race, age and gender.

Intervention: All patients in the experiment group received CRNP alone. We will exclude combination of CRNP with any other interventions.

Comparator: All participants in the control group undertook any management, but not the CRNP.

Study designs to be included: We will include relevant randomized controlled trials on assessing the efficacy and safety of NNIB for the treatment of CRNP.

Eligibility criteria: We will include relevant randomized controlled trials (RCTs) on assessing the efficacy and safety of NNIB for the treatment of CRNP. We will exclude any other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCTs.

Information sources: Studies will be identified by searching the following electronic databases from inception to the March 1, 2019: Cochrane Library, PubMed, EMBASE, Web of Science, PsycINFO, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine Database, Chinese Biomedical Literature Database and China National Knowledge Infrastructure. No restrictions of language and publication status will be imposed in this study. The sample of search strategy for Cochrane Library will be made. We will also adapt similar search strategies to the other electronic databases. Additionally, this study will also search any relevant conference proceedings, dissertations, sources of clinical trial registry, and reference lists of associated reviews.

Main outcome(s): The primary outcomes are nasal symptoms and polyp sizes. Nasal symptoms are assessed using Visual analogue scales, or other relevant scales. Polyp sizes are measured using Kennedy scores or other associated scores. The secondary outcomes are serum cortisol levels, health-related quality of life (as checked using 36-Item Short Form Survey or other tools), and any expected and unexpected adverse events.

Data management: After study selection, all important data will be collected using a data collection sheet, which will be piloted on the eligible studies before being finalized by two independent reviewers. Any disagreements between two reviewers over the data collection will be discussed, and a third reviewer will be consulted to reach a consensus. If there are multiple studies which utilized the same data sources, they will be noted separately in data collection as they may provide views to different covariates, and mediators. The following information will be collected: study characteristics (such as title, first author, year of publication, country, et al), patient characteristics (such as race, age, gender, diagnostic criteria, inclusion and exclusion criteria, et al), study setting, sample size, study methods (such as details of randomization, blind, concealment, et al), details of interventions and controls (such as types of interventions, controls, dosage, duration, et al), relevant outcome measurements, any expected and unexpected adverse events, and funding information.

Quality assessment / Risk of bias analysis: All included studies will be evaluated using Cochrane risk of bias tool for RCTs. It is recommended by the Cochrane Handbook. It covers seven aspects and each one is further graded as low risk of bias, unclear risk of bias or high risk of bias. All study quality assessment will be independently carried out by two reviewers. Any divergences between two reviewers will be solved by a third reviewer through discussion to reach a final decision.

Strategy of data synthesis: RevMan 5.3 Software will be applied for statistical analysis in this study. All continuous values will be exerted as mean difference or standardized mean difference and 95% confidence intervals (CIs), while all

dichotomous values will be presented as risk ratio and 95% CIs. The heterogeneity among included studies will be identified using I^2 statistic test and will be interpreted as follows: I^2 ≤50% means low level of heterogeneity, and a fixed-effects model will be utilized to pool the data; while I^2 >50% indicates high level of heterogeneity, and a random-effects model will be used to synthesize the data. If low level of heterogeneity among included is identified, we will perform a meta-analysis if necessary. On the other hand, if there is a high degree of heterogeneity among primary RCTs, including different characteristics of study or patient, study designs, interventions and controls, which will limit our ability to carry a meta-analysis. Then, we will conduct a subgroup analysis to investigate possible reasons that may result in such obvious heterogeneity.

Subgroup analysis: We will conduct subgroup analysis according to the different characteristics of study or patient, different interventions or controls, and different outcome measurements.

Sensibility analysis: If necessary, we will also perform sensitivity analysis to check the robustness of pooled outcome results by removing low quality studies.

Country(ies) involved: China.

Keywords: Chronic rhinosinusitis; nasal polyps; nasal nebulization inhalation; budesonide; efficacy; safety.