INPLASY PROTOCOL

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

Conflicts of interest: **None.**

Efficacy of levocetirizine for the treatment of children with allergic rhinitis: a protocol for systematic review and meta-analysis

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

Review question / Objective: **Is levocetirizine effective and safety for the treatment of children with allergic rhinitis (AR)?**
Condition being studied: **Levocetirizine; allergic rhinitis; children.**
Information sources: **We will carry out a comprehensive search including MEDLINE, EMBASE, The Cochrane Library, CINAHL, ACMD, PsycINFO, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from their beginning to the present without restrictions of language and publication status. The detailed search strategy for MEDLINE is created with the help of a professional librarian. We will also adapt similar search strategies to the other electronic databases. Further searches will be conducted for abstracts of scientific conferences/ symposia, or reference lists of relevant reviews or clinical trial registries for ongoing trials.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 April 2020 and was last updated on 18 April 2020 (registration number INPLASY202040111.

INTRODUCTION

Review question / Objective: **Is levocetirizine effective and safety for the treatment of children with allergic rhinitis (AR)?**

Condition being studied: **Levocetirizine; allergic rhinitis; children.**

METHODS

Participant or population: **Any children (below 18 years old) diagnosed with AR will be included regardless their country, race, gender, and economic background.**

Intervention: **We will accept any forms of levocetirizine as an interventional**

treatment in the experimental group. However, we will remove studies with combination of levocetirizine and other modalities.

Comparator: In the control group, we accept any treatments, except any types of levocetirizine, including its single or combination modes.

Study designs to be included: Types of studies are randomized controlled trials (RCTs) on investigating the efficacy and harms of levocetirizine for children with AR.

Eligibility criteria: Types of studies are RCTs on investigating the efficacy and harms of levocetirizine for children with AR regardless their publication type, publication time and language. We will not consider any other studies, such as reviews, case studies.

Information sources: We will carry out a comprehensive search including MEDLINE, EMBASE, The Cochrane Library, CINAHL, ACMD, PsycINFO, Chinese Biomedical Literature Database, and China National Knowledge Infrastructure from their beginning to the present without restrictions of language and publication status. The detailed search strategy for MEDLINE is created with the help of a professional librarian. We will also adapt similar search strategies to the other electronic databases. Further searches will be conducted for abstracts of scientific conferences/ symposia, or reference lists of relevant reviews or clinical trial registries for ongoing trials.

Main outcome(s): The primary outcome is total nasal symptoms. It consists of nasal symptoms (sneezing, runny nose, nasal itching, and nasal congestion) and ocular symptoms (eye itching, foreign body sensation, red eyes, tearing). It can be measured by any appropriate scales or other forms of tools, such as the Total Nasal Symptom Score. The secondary outcomes are quality of life (as identified by any scores, such as the Rhinoconjunctivitis Quality of Life Questionnaire), global non-nasal symptoms (as assessed by any validated daily or weekly diaries or scores, such as visual analogue scales), use of conventional medication (as evaluated by Medication Quantification Scale or any other scales), laboratory indicators, and any expected or unexpected adverse events.

Data management: Two authors will independently extract data from included trials using data collection sheet, which has been piloted on at least two trials. Any inconsistent views will be solved by involving a third experienced author. We will collect the following information: Trial characteristics: title, first author, year of publication, et al; Patient characteristics: race, gender, age, diagnostic criteria, inclusion and exclusion criteria, number of patients, et al; Methods: trial design, trial setting, details of randomization, blind, et al; Interventions and controls: delivery modes, dosage, frequency, duration, et al; Outcomes: primary and secondary outcomes, any expected and unexpected adverse events, et al; Others: funding for trial, conflict of interests of study authors. If we identified any insufficient or missing information, we will contact original authors to obtain them. If these data are not available, we will only utilize the available data for statistical analysis. Additionally, we will also discuss its potential impacts as limitation in the manuscript.

Quality assessment / Risk of bias analysis: Two authors will independently evaluate the risk of bias for each eligible trial using Cochrane risk of bias tool. It covers aspects of allocation sequence generation, allocation concealment, blinding of participants and treatment providers, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other bias. Each aspect is further judged as low, unclear or high risk of bias. In case of disagreements, a third author will to help resolve them by consultation.

Strategy of data synthesis: For continuous data, we will calculate it using standardized mean difference and different unit and 95%

confidence intervals (CIs). For dichotomous data, we will elaborate it using risk ratio and 95% CIs. We will assess the presence of statistical heterogeneity by using I^2 statistic test and will interpret its values as follows: I^2 ≤50% exerts acceptable heterogeneity, while I^2 >50% presents significant heterogeneity. If I^2 ≤50%, we will use a fixed-effects model. If sufficient data are obtained, we will synthesize the data and will conduct a meta-analysis. Otherwise, if I^2 >50%, we will apply a random-effects model. We will also carry out subgroup analysis to explore the possible reasons for the substantial analysis. We will also report narrative synthesis based on the available data. We will combine quantitative data for each outcome of symptoms, for example, we will report the mean for total nasal symptoms (e.g. Total Nasal Symptom Score), or we will report global non-nasal symptoms (e.g. validated daily or weekly diaries or scores). We will also combine data from quality of as (e.g. Rhinoconjunctivitis Quality of Life Questionnaire), use of conventional medication (e.g. Medication Quantification Scale or any other scales) and laboratory indicators if they are reported in the same format. If the data is reported inconsistently (e.g. incidence of adverse events), we will summarize such kind of information qualitatively in the narrative synthesis.

Subgroup analysis: We will undertake subgroup analysis based on the different types of interventions and controls, characteristics of study or patient, and different outcome measurements.

Sensibility analysis: In the case of sufficient data, we will carry out sensitivity analysis to check the robustness of pooled outcome results based on the study characteristics, or methodological quality by excluding high risk of bias trials.

Country(ies) involved: China.

Keywords: Levocetirizine; allergic rhinitis; children; efficacy; safety.