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# Meta-analysis of the efficacy and safety of Cimetidine Combined with Montelukast in the treatment of Henoch-Schonlein Purpura (HSP) in children

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#### **ADMINISTRATIVE INFORMATION**

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Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023100097

**Amendments -** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 31 October 2023 and was last updated on 31 October 2023.

#### INTRODUCTION

Review question / Objective This study aims to evaluate the clinical efficacy and safety of Cimetidine combined with Montelukast in treating children with Henoch-Schonlein Purpura (HSP).

Condition being studied Henoch-Schonlein Purpura (HSP) is a common systemic vasculitis in children, that incidence rate is 13.5-18.0/100000. It primarily affects children under 10 years old, with no significant difference between males and females. Current treatment for HSP is mainly supportive and symptomatic, supplemented with glucocorticoid and immunosuppressive treatment when necessary. However, the efficacy of many drugs requires further verification through clinical trials. Recent studies have indicated that combining Cimetidine with Montelukast yields promising

results in treating children with HSP. Therefore, this study conducted a meta-analysis to further clarify its efficacy and safety.

# **METHODS**

**Participant or population** Patients who were diagnosed with HSP aged 1-18 years and without limitations in gender and race.

**Intervention** Cimetidine combined with Montelukast.

**Comparator** Nither conventional treatment or conventional treatment combined with Cimetidine or Montelukast.

Study designs to be included Randomized Controlled Trial.

**Eligibility criteria** Patients who were diagnosed with HSP aged 1-18 years and without limitations in gender and race.

Information sources We will search RCT studies related to the treatment of children with HSP using Cimetidine combined with Montelukast was conducted in the following databases: CNKI, VIP Journal Network, China Biomedical Literature Database, Wanfang Data Knowledge Service Platform, PubMed, Embase, and The Cochrane Library. The search period ranged from the establishment of the database until August 21, 2023.

Main outcome(s) Efficiency, regression time of purpura, regression time of joint swelling, regression time of abdominal pain, regression time of gastrointestinal reactions, regression time of rash, recurrence rate, and adverse reactions.

Quality assessment / Risk of bias analysis The quality of the included RCTs was evaluated by the risk of bias assessment tool of Cochrane Handbook for Systematic Reviews of Interventions(Version 5.1.0). The biases mainly covered six aspects, namely, selection bias, performance bias, detection bias, attrition bias, reporting bias and other biases, and were categorized with "low risk", "unclear risk" and "high risk" one by one.

**Strategy of data synthesis** Data analysis was conducted using RevMan5.3 and Stata12.0.The P and I2 values were used to assess the heterogeneity.

**Subgroup analysis** Subgroup analysis was conducted according to the treatment scheme and the duration of treatment.

Sensitivity analysis When P > 0.1 and I2  $\leq$  50%, no heterogeneity was assumed, and the fixed effect model was used for analysis. When P  $\leq$  0.1 and I2 > 50%, indicating heterogeneity, the random effect model was selected, and the source and sensitivity were analyzed.

Country(ies) involved China.

**Keywords** Henoch-Schonlein Purpura (HSP); Cimetidine; Montelukast; meta-analysis Children.

#### Contributions of each author

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