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Efficacy and safety of bacterial lysates in the treatment of adults and children asthma：meta-analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 7 November 2024 and was last updated on 7 November 2024.

INTRODUCTION

Review question / Objective Population:adults and children with asthma; Intervention:oral bacterial lysates; Comparison:inhaled corticosteroids and other treatment; Outcome:Frequency of asthma attacks,wheezing days, Frequency of respiratory infections, FEV1, PEF, FVC, Therapeutic effectiveness.

Condition being studied Bronchial asthma is a common chronic airway inflammatory disease in adults and children, which seriously affects the quality of life of patients and even endangers the life of patients with acute and critical attacks. Inhaled glucocorticoids (ICS) is an important first-line anti-inflammatory drug in the treatment of asthma, but there are still some patients with poor control, acute respiratory infection (RTI) is one of the important risk factors. With the deepening of research on the role of immune imbalance mechanism in asthma, immunomodulatory agents such as bacterial lysates have been paid more and more attention. In recent years, more and more studies have found the immunomodulatory effects of bacterial lysate products, which have been confirmed in some allergic diseases. After preliminary studies, we found that there has been no in-depth systematic review of whether oral bacterial lysates are safe and effective in patients with asthma. Therefore, we used this protocol to comprehensively evaluate the efficacy of oral bacterial lysates in the treatment of asthma.

METHODS

Participant or population All adults and children with asthma will be included without limitation of sex, race, economic level,severity.

Intervention Bacterial lysates.

Comparator Inhaled glucocorticoids.

Study designs to be included Only randomized controlled trials(RCTs) will be included in this study.

Eligibility criteria We will include only the literature of randomized controlled trials(RCTs) of bacterial lysates for adults and children with asthma.Nonrandomized controlled studies,case reports,case series and reviews will not be included in this study.

Information sources Related studies in the following databases will be searched from inception to October 31,2024:PubMed, EMBASE,Web of Science,the Cochrane Library, China National Knowledge Infrastructure(CNKI), Wanfang, and VIP.

Main outcome(s) Frequency of asthma attacks,wheezing days, Frequency of respiratory infections,FEV1,PEF,FVC,Therapeutic effectiveness.

Quality assessment / Risk of bias analysis The quality of all RCTs will be evaluated with the Cochrane Collaboration tool.Two authors(Lingling Chen and Yaping Ying)will independently conduct quality evaluations,and any controversy will be addressed by discussion with another author(Xiaohong Jin).

Strategy of data synthesis The meta-analysis of data from included outcomes will be performed using the RevMan V.5.4.1, and we will choose a randomized or fixed effect model for data statistics according to the results of the heterogeneity test. The enumeration data were expressed as relative risk (RR), and the weight mean difference (WMD) was used as the measurement data; each effect amount was expressed in 95% confidence interval (CI). The specific methods were as follows:If the heterogeneity was low (I^2 50%), the random-effects model will be used for data synthesis after excluding possible heterogeneity sources. The investigation methods included subgroup and sensitivity analyses. If data cannot be synthesized, we provide a descriptive analysis to solve this problem.

Subgroup analysis If there was high heterogeneity (I^2 > 50%) among the included studies, we conducted a subgroup analysis to analyze the sources of heterogeneity according to the following factors: age ,sex, races,courses, sample sizes, and other possible factors affecting the results. If necessary, we will conduct a subgroup analysis of the different doses of the drug, treatment time, different courses of asthma.

Sensitivity analysis To test the stability and reliability of the results of this study, we conducted a sensitivity analysis according to the following points: method quality, sample size, and missing data. After that, we will perform a data analysis again and compare the results. If there was no directional change after the sensitivity analysis, the results were stable.

Country(ies) involved People's Republic of China.

Keywords asthma;bacterial lysates; immunoregulation.

Contributions of each author

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