INPLASY PROTOCOL

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None declared.

Meta-analysis of the relationship between montelukast use and neuropsychiatric events in patients with allergic rhinitis and/or asthma

Mou, YK; Song, Q; Zhao, CY; Fang, H; Liu, JH; Ren, C; Song, XC[4].

Review question / Objective: **Population: patients with allergic rhinitis and/or asthma; Intervention: patients use montelukast and the occurrence of neuropsychiatric events (NEs); Comparison: patients not use montelukast and the occurrence of neuropsychiatric events (NEs); Outcome: The incidence of NE events was different between the intervention and Comparison; Study design: randomized controlled trials (RCTs).**
Condition being studied: **The use of montelukast has been controversial as a cause of neuropsychiatric events in patients with asthma or allergic rhinitis. There is no statistical analysis to verify the relationship. In order to better understand the relationship between montelukast and neuropsychiatric events, it is of vital importance to effectively guide patients to use montelukast.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 January 2023 and was last updated on 17 January 2023 (registration number INPLASY202310051).

INTRODUCTION

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patients with asthma or allergic rhinitis. There is no statistical analysis to verify the relationship. In order to better understand the relationship between montelukast and neuropsychiatric events, it is of vital importance to effectively guide patients to use montelukast.

METHODS

Participant or population: Patients with allergic rhinitis and/orasthma.

Intervention: Patients use montelukast.

Comparator: Patients not use montelukast.

Study designs to be included: Randomized controlled trials (RCTs).

Eligibility criteria: Studies were included if they met the following criteria: (i) montelukast was used to treat patients with allergic rhinitis and/or asthma; (ii) randomized controlled trials; (iii) full text could be found online and published in English language; (iiii) the study provided available data for analysis.

Information sources: We conducted a comprehensive survey of patients with allergic rhinitis and/or asthma who used montelukast to analyze the possibility of NEs. MEDLINE (1966 to September 2022), Embase (1974 to September 2022), Web of Science databases, and ref-erence lists of the retrieved studies were used.

Main outcome(s): The main results showed no significant increase in neuropsychiatric events compared with the placebo group. Similar results were seen in the oc-currence of neuropsychiatric events in patients grouped by age and headache that the most common neuropsychiatric adverse event. Overall, montelukast did not significantly increase neuropsychiatric events in patients with allergic rhinitis and/or asthma compared with placebo.

Quality assessment / Risk of bias analysis: The quality of the included studies was assessed by Jadad scale. Each study can be assessed by methods (method of patient random allocation, concealment of alloca-tion, blinding and data loss to follow). Afterward, the Cochrane Handbook for Systematic Reviews of Interventions v.5.1.0. was used to grade individual studies. Each study was assigned a category: A, low risk of bias where the study met almost the criteria; B, moderate risk of bias where the study met part or unclear for one or more quality criteria; C, high risk of bias where the study did not meet or included the criteria.

Strategy of data synthesis: The STATA 12.0 package (Stata Corp, College Station, TX, USA) was used to analyze the data. Fixed or random effect models will be used to combine statistics. The relative risk (RR) was used to estimate dichotomous outcomes and the 95% confidence interval (CI). I2 test and x2 based Q statistics were used to assess the heterogeneity of the study. If I2 value >50% or p-value <0.1, then the heterogeneity of the study was significant, and the fixed effect model was used to analyze the study. Otherwise, the random effect model was used. If p-value was less than 0.05, then the result was considered statistically significant.

Subgroup analysis: Subgroup studies were conducted in children or adults.

Sensitivity analysis: The stata software is used to perform sensitivity analysis, which determines the sensitivity of an article by observing the effect change after it has been deleted.

Country(ies) involved: China.

Keywords: allergic airway disease; montelukast; neuropsychiatric event; children.

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