INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effectiveness and safety of Suhuang Zhike Capsule in combination with budesonide in the treatment of cough variant asthma in adults: a systematic review and meta-analysis

Hong, Z[1]; Liu, Y[2]; Fang, HY[3]; Yu, B[4]; Zhang, HC[5].

Review question / Objective: **To determine the effectiveness and safety of Traditional Chinese Medicine- Suhuang Zhike Capsule in combination with budesonide in the treatment of cough variant asthma (CVA) in adults.**
Information sources: **We will search the following electronic databases for studies on CVA treatment uploaded since their inception to September 9, 2022. .The Cochrane Central Register of Controlled Trials (CENTRAL) -PubMed (1966 to September 2022) -Web of Science (1986 to September 2022) -EMBASE (1980 to September 2022) -China Biomedical Database (1975 to September 2022) (http://www.sinomed.ac.cn). China National Knowledge Infrastructure (CNKI) (1979 to September 2022) (http://www.cnki.net/) VIP Database (1979-September 2022) (http://www.cqvip.com/) . Wanfang Database (1980- September 2022) (http://wwwwanfangdata.com.cn). We will search the following electronic databases for studies on CB or COPD treatment uploaded since their creation until September 9, 2022.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 September 2022 and was last updated on 17 September 2022 (registration number INPLASY202290082).

INTRODUCTION

Review question / Objective: **To determine the effectiveness and safety of Traditional Chinese Medicine- Suhuang Zhike Capsule in combination with budesonide in the treatment of cough variant asthma (CVA) in adults.**

Condition being studied: **Cough variant asthma (CVA), as a phenotype of asthma, is the most common cause of chronic cough, accounting for 32.6% of the causes of**

chronic cough in China, with chronic cough as the main or only clinical manifestation. CVA is characterized by a persistent airway inflammatory response with airway hyperresponsiveness and some efficacy with traditional bronchial asthma therapies such as low-dose inhaled glucocorticoids (ICS). However, it is unclear whether ICS can significantly improve the clinical outcome of CVA patients. Long-term use of ICS may lead to many adverse effects such as hoarseness, pharyngeal discomfort, and Candida infection, as well as poor compliance, and may lead to recurrence or exacerbation of cough and further deterioration of lung function due to inadequate anti-inflammatory therapy. TCM is expected to be the most promising complementary or alternative drug in the pharmacological treatment of CVA. Suhuang Zhike Capsule by Professor Chao Enxiang, a master of Chinese medicine, is widely used in the treatment of chronic cough, especially CVA, and are recommended by the Chinese Medical Association's 2021 Guidelines for the Diagnosis and Treatment of Cough as the only proprietary Chinese medicine for the treatment of post-infectious cough and CVA. Although Suhuang Cough Capsules are favored by clinicians and patients, at the same time, budesonide is one of the widely used ICS at this stage of clinical use. however, there is little evidence regarding the combination of Suhuang Zhike Capsule with budesonide for the treatment of CVA, which does not provide strong evidence to support clinical decision-makers. Therefore, the purpose of this study was to conduct a systematic review to investigate the efficacy and safety of Suhuang Zhike Capsule in combination with budesonide in adults with CVA.

METHODS

Participant or population: Participants were adults with cough variant asthma diagnosed according to the Global Initiative for Asthma (GINA) or equivalent criteria, such as the Expert Consensus on the Diagnosis and Treatment of Asthma in Chinese Medicine published by the Chinese Medical Association, regardless of gender, etiology, race, and duration of disease. Children with cough variant asthma were excluded. Participants who meet the diagnostic criteria of CVA will be included, including subjects with CVA as defined by the British Medical Research Council.

Intervention: Suhuang Zhike Capsule in combination with budesonide, with or without Long-acting beta-2-receptor agonist(LABA) and long-acting muscarinic antagonist (LAMA).

Comparator: Budesonide with or without LABA and LAMA.

Study designs to be included: RCTs.

Eligibility criteria: Exclusion criteria also include case reports case series and observational studies.

Information sources: We will search the following electronic databases for studies on CVA treatment uploaded since their inception to September 9, 2022. .The Cochrane Central Register of Controlled Trials (CENTRAL) -PubMed (1966 to September 2022) -Web of Science (1986 to September 2022) -EMBASE (1980 to September 2022) -China Biomedical Database (1975 to September 2022) (http://www.sinomed.ac.cn). China National Knowledge Infrastructure (CNKI) (1979 to September 2022) (http://www.cnki.net/) VIP Database (1979-September 2022) (http://www.cqvip.com/) . Wanfang Database (1980- September 2022) (http://wwwwanfangdata.com.cn). We will search the following electronic databases for studies on CB or COPD treatment uploaded since their creation until September 9, 2022.

Main outcome(s): Pulmonary function (FEV1,PEF), Sputum eosinophil percentage, Adverse reaction.

Quality assessment / Risk of bias analysis: Two reviewers (Hong Z, Liu Y) independently assessed the risk of bias for each included trial according to the Cochrane Handbook for Systematic

Reviewers of Interventions, 5th edition, for items including random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessments (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and comparability of baseline data (other bias). Each item was categorized as low/unclear/high risk of bias. Disagreements were resolved by discussion, involving a third reviewer (Zhang HC) when necessary. In addition, we used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to assess the quality of the included evidence.

Strategy of data synthesis: Continuous results will be expressed as mean difference (MD) and dichotomous results as risk ratio (RR), both with 95% confidence intervals (CI). We will use a random-effects model to estimate the overall effect rather than a fixed-effects model because a random-effects model provides more conservative results by assessing study outcomes based on within-trial and between-trial differences.

Subgroup analysis: Subgroup analysis will be carried out according to the different course of treat by Suhuang Zhike Capsule.

Sensitivity analysis: The sensitivity analysis was also performed by removing each study one at a time to evaluate the stability of the results.

Country(ies) involved: China, United States.

Keywords: Suhuang Zhike Capsule; Budesonide; CVA; RCTs; systemic review; meta analysis.

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