INPLASY PROTOCOL

To cite: Liu et al. Effectiveness and safety of Suhuang Zhike Capsule for acute exacerbations of Chronic Bronchitis or Chronic Obstructive Pulmonary Disease in adults :a systematic review and meta-analysis. Inplasy protocol 202280084. doi: 10.37766/inplasy2022.8.0084

Received: 22 August 2022

Published: 22 August 2022

Corresponding author:
Liu Ying

liuyingbucm@163.com

Author Affiliation:
China-Japan Friendship Hospital.

Support: **NO.2019YFC1712000; No. 2020YB26.**

Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None declared.

Effectiveness and safety of Suhuang Zhike Capsule for acute exacerbations of Chronic Bronchitis or Chronic Obstructive Pulmonary Disease in adults :a systematic review and meta-analysis

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

Review question / Objective: **To determine the effectiveness and safety of Traditional Chinese Patent Medicine-Suhuang Zhike Capsule in the treatment of acute exacerbations of Chronic Bronchitis(CB) or Chronic Obstructive Pulmonary Disease(COPD) in adults.**
Condition being studied: **COPD is currently the fourth leading cause of death in the world.There are world-wide concerns about the high morbidity of COPD and its serious economic and social burdens. Recurrent exacerbations of chronic bronchitis or COPD are the main factors leading to disease progression.At present, there are many treatment methods and drugs for the disease, including glucocorticoids, bronchodilators, antibiotics and so on.However, these methods still cannot meet the needs of CB or COPD patients. The patients may benefit from additional treatment options such as herbal medicines. In recent years, Suhuang Zhike capsule has been widely used in respiratory diseases (such as Cough Variant Asthma, postinfection cough, COPD, etc). The results show that it can reduce the clinical symptoms of CB or COPD exacerbations, shorten the course of disease, improve the lung function of the patients. However, there is little evidence concerning its effectiveness and safety for CB or COPD patients. Therefore, the aim of this study is to conduct a systematic review to explore the effectiveness and safety of Suhuang Zhike Capsule on CB or COPD exacerbations in adults.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 August 2022 and was last updated on 22 August 2022 (registration number INPLASY202280084).

INTRODUCTION

Review question / Objective: **To determine the effectiveness and safety of Traditional Chinese Patent Medicine-Suhuang Zhike Capsule in the treatment of acute exacerbations of Chronic Bronchitis(CB) or Chronic Obstructive Pulmonary Disease(COPD) in adults.**

Condition being studied: COPD is currently the fourth leading cause of death in the world.There are world-wide concerns about the high morbidity of COPD and its serious economic and social burdens. Recurrent exacerbations of chronic bronchitis or COPD are the main factors leading to disease progression.At present, there are many treatment methods and drugs for the disease, including glucocorticoids, bronchodilators, antibiotics and so on.However, these methods still cannot meet the needs of CB or COPD patients. The patients may benefit from additional treatment options such as herbal medicines. In recent years, Suhuang Zhike capsule has been widely used in respiratory diseases (such as Cough Variant Asthma, postinfection cough, COPD, etc). The results show that it can reduce the clinical symptoms of CB or COPD exacerbations, shorten the course of disease, improve the lung function of the patients. However, there is little evidence concerning its effectiveness and safety for CB or COPD patients. Therefore, the aim of this study is to conduct a systematic review to explore the effectiveness and safety of Suhuang Zhike Capsule on CB or COPD exacerbations in adults.

METHODS

Participant or population: Participants who meet the diagnostic criteria of CB or COPD will be included, including subjects with CB as defined by the British MedicalResearch Council, COPD as defined by the criteria of the AmericanThoracic Society, the Global Initiative for Chronic Obstructive Lung Disease (GOLD), the European Respiratory Society, or the WorldHealth Organization (WHO).

Intervention: On the basis of conventional therapy, Suhuang Zhike Capsule were added.

Comparator: The comparative intervention was defined that treatment of CB or COPD exacerbations is based on Global Initiative for Chronic Obstructive Lung Disease (GOLD) or Treatment of COPD published by the Chinese Medical Association which includes glucocorticoids, bronchodilators, antibiotics and so on.

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 database for studies on the treatment of CB or COPD uploaded since the establishment until August 20,2022:

- The Cochrane Central Register of Controlled Trials (CENTRAL)
- PubMed (1966 to August 2022)
- Web of Science (1986 to August 2022)
- EMBASE (1980 to August 2022)
- Chinese Biomedical Database (1975 to August 2022)（http://www.sinomed.ac.cn）
- China National Knowledge Infrastructure (CNKI) (1979 to August 2022) （http://www.cnki.net/）
- VIP database (1979 to August 2022)（http://www.cqvip.com/）
- Wan fang Database (1980- August 2022)（http://www.wanfangdata.com.cn）
- We will search the following electronic database for studies on the treatment of CB or COPD uploaded since the establishment until August 20, 2022.

Main outcome(s): Disappearance time of cough; pulmonary function(FEV1/FVC,FEV1,FVC); Adverse reaction.

Additional outcome(s): TNF;IL-8;IL-6.

Quality assessment / Risk of bias analysis: Two reviewers (Liu Y, Hong Z) independently assessed the risk of bias for each included trial according to the Cochrane Handbook for Systematic Reviewers of Interventions version 5. The items included random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data

(attrition bias), selective reporting (reporting bias), and baseline data comparability (other bias). Each item was categorized as low/unclear/high risk of bias. Disagreements were resolved by discussion, with involvement of a third review author (Zhang HC) when necessary. In addition, we used the grading of recommendations assessment, development, and evaluation (GRADE) approach to evaluate the quality of included evidences.

Strategy of data synthesis: Continuous outcomes will be presented as mean difference (MD), and dichotomous outcomes as risk ratio (RR), both with 95% confidence intervals (CI). We will use a random-effects model to estimate the overall effect instead of a fixed-effect model, because random-effects models assess the outcomes of the study according to within-trial as well as between-trial variance, thus providing more conservative results.

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.

Keywords: Suhuang Zhike Capsule; COPD; CB; RCTs; systemic review; meta analysis.

Contributions of each author:
Author 1 - Ying Liu.
Author 2 - Hanyu Fang.
Author 3 - Zheng Hong.
Author 4 - Yu Ming.
Author 5 - Hongchun Zhang.