INPLASY PROTOCOL

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None declared.

Efficacy and safety of Chuankezhi injection for treating acute exacerbation of chronic bronchitis: a protocol for systematic review and meta-analysis

Gao, Y[1]; Wang, S[2]; Yin, K[3]; Yuan, Y[4]; Gong, XY[5].

Review question / Objective: **Types of studies: We will collect randomized controlled trials (RCTs) that were published or registered before to 1 March 2022 to evaluate efficacy and safety of CKZ in the treatment of CB for systematic review and meta-analysis. Types of patients: Participants who were diagnosed with the acute exacerbation of chronic bronchitis by age ≥ 18 years old without limitations related to gender, race, study area, and education status. Types of interventions: In the intervention group, patients received CKZ or combined with Western medicine. In the control group, patients received no treatment, placebo, or western medication. Comparisons to be examined included the following. Types of outcome measures: The primary outcomes will include the Cough Scale score, Sputum Scale score, Change in Breathlessness, and clinical effective rate. The secondary outcomes will include adverse effects.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 March 2022 and was last updated on 08 March 2022 (registration number INPLASY202230036).

INTRODUCTION

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Condition being studied: We will analyze the data with Rev Man software (Version 5.4)(Available at: https://community.cochrane.org/help/tools-and-software/revman-5) provided by The Cochrane Collaboration. A meta-analysis using random or fixed effects models will be conducted to summarize the data. Continuous data will be pooled and presented as mean differences or standardized mean difference with their 95% CI. Dichotomous data will be pooled and expressed as risk ratio with their 95% CI. We will interpret it using the following criteria: I2values of 25% is considered low levels of heterogeneity, 50% indicated moderate levels, and 75%indicated high levels.Since low or moderate heterogeneity suggests little variability among these studies, the data will be analyzed in a fixed-effects model.[20]When significant heterogeneity occurs among the studies (P < .05, I2> 50%), a random-effect model will be performed to analyze the data.

METHODS

Participant or population: Participants who were diagnosed with the acute exacerbation of chronic bronchitis by age ≥ 18 years old without limitations related to gender, race, study area, and education status.

Intervention: In the intervention group, patients received CKZ or combined with Western medicine.

Comparator: In the control group, patients received no treatment, placebo, or western medication.Comparisons to be examined included the following.

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

Eligibility criteria: Inclusion criteria were: participants who were diagnosed acute exacerbation of chronic bronchitis; CKZ as the intervention; randomized controlled trials (RCT); the Cough Scale score, Sputum Scale score, Change in Breathlessness, and clinical effective rate.

Information sources: Two reviewers (YG and SW) independently searched the China National Knowledge Infrastructure(CNKI), the Chinese Biomedical Literature Database (CBM), Wanfang Data (WAN FANG), the Chinese Scientific Journal Database (CSJD), the Cochrane Central Register of Controlled Trials, the Web of Science, PubMed and Embase databases from inception to 1 March 2022. Except for electronic search, we will also hand search the conference summary and trial register.

Main outcome(s): The primary outcomes will include the Cough Scale score, Sputum Scale score, Change in Breathlessness, and clinical effective rate.

Quality assessment / Risk of bias analysis: Two review authors (YG and SW) will assess the internal validity of included studies by using the Cochrane Handbook for Systematic Reviews of Interventions. The following domains will be assessed: random sequence generation and allocation concealment (selection bias), incomplete outcome data (attrition bias), outcome assessment (detection bias), selection of the reported result (reporting bias), and other biases (such as pre-sample size estimation, early stop of trial). Results from these questions will be graphed and assessed using Review Manager 5.4 (https://community.cochrane.org/help/tools-and-software/revman-5). Each item will be evaluated in three categories: low risk of bias, unclear bias, and high risk of bias. Any discrepancies will be resolved by discussing with the third author (KY) to reach a consensus.

Strategy of data synthesis: Two review authors (YG and SW) will independently

evaluate the titles and abstracts of all citations found from the above search strategy. We will obtain the full text of all potentially suitable articles to further assess eligibility based on the inclusion/exclusion criteria.Two reviewers(YG, SW) will independently extract data using a data extraction form according to the recommendations of the Cochrane Handbook for Systematic Reviews of Interventions. The following data will be extracted: study characteristics such as author, year of publication, country where the study was conducted, study period, original inclusion criteria, total number of people included in the study; population characteristics such as type of respiratory disease, mean age, and time from diagnosis; intervention characteristics such as type, injection frequency, and medication methods; outcomes such as the Cough Scale score, Sputum Scale score, Change in Breathlessness, and clinical effective rate.

Subgroup analysis: We plan to carry out the following subgroup analyses to explore possible sources of heterogeneity: the severity of CB, course of the disease, medication methods, and treatment frequency. If the data is insufficient, the qualitative synthesis will be conducted instead of the quantitative synthesis.

Sensitivity analysis: When possible, we will perform sensitivity analysis by eliminating low-quality trials to explore the effects of the trial's bias risk on primary outcomes.

Country(ies) involved: China.

Keywords: chronic bronchitis; acute exacerbation; Chuankezhi injection; systematic review; meta-analysis; protocol.

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