INPLASY PROTOCOL

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Conflicts of interest:
None.

Efficacy and safety of Shufeng Jiedu Capsule in the treatment of acute exacerbations of chronic obstructive pulmonary disease: A protocol for systematic review and meta-analysis

Ren, H[1]; Jiang, Y[2]; Wang, S[3]; Wang, Y[4]; Wang, J[5].

Review question / Objective: **The purpose of this study was to evaluate the efficacy and safety of Shufeng Jiedu Capsule in the treatment of AECOPD.**
Condition being studied: **With the outbreak of novel coronavirus, the treatment of respiratory diseases has been promoted. In particular, many traditional Chinese medicines, including Chinese patent medicines, have been found to be effective in the treatment of respiratory illness in China. COPD is one of most common respiratory condition. It is predicted that COPD will be become the third frequent cause of death by 2030. Shufeng Jiedu (SFJD) capsule, which is an oral patent Chinese herbal medicine, used widely in China for the treatment of respiratory disease. Eight medicinal herbs make up this capsule, which contains Rhizoma Polygoni Cuspidati, Fructus Forsythiae, Radix Isatidis, Radix Bupleuri, Herba Patriniae, Herba Verbenae, Rhizoma Phragmitis and Radix Glycyrrhizae. Recently, the basic research on Shufeng Jiedu Capsule shows that it can improve the lung function and reduce the inflammatory index by anti-inflammatory, immunomodulating and antiviral properties. However, there are many new RCTs recently, which have not been included in the previous systematic evaluation. It is necessary to reevaluate its efficacy and safety. So the aim of this study is to assess the efficacy and safety of Shufeng Jiedu Capsule in the treatment of AECOPD.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 December 2020 and was last updated on 11 December 2020 (registration number INPLASY2020120062).

INTRODUCTION

Review question / Objective: **The purpose of this study was to evaluate the efficacy and safety of Shufeng Jiedu Capsule in the treatment of AECOPD.**

Condition being studied: With the outbreak of novel coronavirus, the treatment of respiratory diseases has been promoted. In particular, many traditional Chinese medicines, including Chinese patent medicines, have been found to be effective in the treatment of respiratory illness in China. COPD is one of most common respiratory condition. It is predicted that COPD will be become the third frequent cause of death by 2030. Shufeng Jiedu (SFJD) capsule, which is an oral patent Chinese herbal medicine, used widely in China for the treatment of respiratory disease. Eight medicinal herbs make up this capsule, which contains Rhizoma Polygoni Cuspidati, Fructus Forsythiae, Radix Isatidis, Radix Bupleuri, Herba Patriniae, Herba Verbenae, Rhizoma Phragmitis and Radix Glycyrrhizae. Recently, the basic research on Shufeng Jiedu Capsule shows that it can improve the lung function and reduce the inflammatory index by anti-inflammatory, immunomodulating and antiviral properties. However, there are many new RCTs recently, which have not been included in the previous systematic evaluation. It is necessary to reevaluate its efficacy and safety. So the aim of this study is to assess the efficacy and safety of Shufeng Jiedu Capsule in the treatment of AECOPD.

METHODS

Participant or population: All the patients who have been diagnosed with AECOPD will be included, regardless of their age, gender, or race.

Intervention: SFJD (capsules, granules, or other types) alone or paired with other routine western medicine will be included. There is no limitation regarding the place of origin, dosage form, dosage, frequency and duration of treatment.

Comparator: The comparisons will be either with other therapeutic agents, or without other treatment or placebo based on conventional treatment of western medicine

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

Eligibility criteria: The PICOS principles were given full consideration to establish the inclusion and exclusion criteria of this systematic review.

Information sources: Studies were obtained from the PubMed, Embase and Cochrane Library, China National Knowledge Infrastructure (CNKI), Wan Fang Data, Chinese Scientific Journals Database (VIP), regardless of publication date or language.

Main outcome(s): 1. total efficacy 2. the number of patients who had any adverse events at the end of treatment.

Quality assessment / Risk of bias analysis: Two researchers (Jingying Wang and Huijun Ren) assessed the quality of the included RCTs independently by utilizing the Cochrane risk of bias assessment tool. As specified by Cochrane Handbook V.5.1.0, the following sources of bias were considered: random sequence generation, allocation concealment, participant blinding, outcome assessor blinding, incomplete outcome data, selective reporting, and other sources of bias. Each domain was rated as having a high, low or unclear risk of bias as appropriate. The 2 reviewers resolved any disagreements through discussion, and a third reviewer (Huijun Ren) was involved if a consensus could not be reached.

Strategy of data synthesis: The meta-analysis was performed with Review Manager 5.4 software. The outcomes were mainly represented by the mean difference (MD) or odds ratio (OR) with 95% confidence intervals, and a P value <.05 was considered significant. The Cochrane Q-test and I2 statistics were used to assess heterogeneity. When P < .1 or I2 > 50% indicated statistical heterogeneity, a random effects model was used to calculate the outcomes; otherwise, the fixed effect model was considered.

Subgroup analysis: If there was high heterogeneity in the studies, we performed

subgroup analysis to explore the differences in age, gender, interventions, and course of disease/treatment. We used funnel plots to identify whether there was small study bias if 10 or more studies were included. The asymmetry of funnel plots suggests the possibility of small study effects, and the results of analysis were explained cautiously.

Sensibility analysis: Sensitivity analysis will be performed to test the robustness of findings if there are sufficient studies included. we will conduct sensitivity analyses by excluding (1) studies with high risks of bias and (2) outliers that are numerically distant from the rest of the data.

Country(ies) involved: China.

Keywords: Shufeng Jiedu ,COPD, AECOPD, protocol, systematic review, traditional Chinese medicine.

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