INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy of shenqi bufei decoction on stable chronic obstructive pulmonary disease patients: A protocol for systematic review and meta-analysis

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Review question / Objective: **Is shenqi bufei decoction Efficacy and safe on stable chronic obstructive pulmonary disease patients.**
Condition being studied: **Stable chronic obstructive pulmonary disease.**
Information sources: **Literature databases: PubMed, EMBASE, CENTRAL, China Biomedical Literature Database, Chinese National Knowledge Infrastructure, Wanfang Data, and VIP Trial registry: Clinicaltrials.gov, and Chinese Clinical Trial Registry. Source of grey literature: reference lists of relevant reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 12 April 2022 and was last updated on 12 April 2022 (registration number INPLASY202240069).

INTRODUCTION

Review question / Objective: **Is shenqi bufei decoction Efficacy and safe on stable chronic obstructive pulmonary disease patients**

Rationale: **Chronic obstructive pulmonary disease is defined as persistent respiratory symptoms and airflow restriction due to airway and / or alveolar abnormalities. In the past decades, COPD has become a serious global public health problem. Chronic obstructive pulmonary disease causes about 300000 deaths worldwide**

every year, making it the third leading cause of death. Traditional Chinese medicine has been used to treat symptoms similar to Chronic obstructive pulmonary disease, such as cough, expectoration or shortness of breath, and has shown beneficial effects for hundreds of years. This paper reports on the protocol for a systematic review and meta-analysis exploring the efficacy of shenqi bufei decoction on stable chronic obstructive pulmonary disease patients.

Condition being studied: Stable chronic obstructive pulmonary disease.

METHODS

Search strategy: English databases will be searched by computer include web of science, PubMed, EMBASE, CINAHL, Cochrane Central Register of controlled trials; China biomedical science and technology database, China biomedical science and technology database (cnking), Chinese Journal Database (cnwang). The retrieval time will be from the establishment of the database to March 25, 2022. The retrieval method will combine subject words and free words. The key words will include "Shenqi Bufei Decoction" [supplementary concept] "Shenqi Bufei" “chronic obstructive pulmonary disease" "chronic obstructive airway di-sease" “chronic obstructive lung disease", "COPD", "coad", "pulmonary disease, chronic obstructive [mesh]" and so on. There will be no restriction on the type and language of literature publication. The search strategy is shown in appendix.

Participant or population: Stable chronic obstructive pulmonary disease patients.

Intervention: The experimental group will be participants treated with the original formula of shenqi bufei decoction or the addition and subtraction formula or combined with conventional Western Medicine.

Comparator: The control group will be treated with conventional western medicine or placebo.

Study designs to be included: The study will be randomized controlled trial.

Eligibility criteria: The subjects will be those who have been diagnosed as stable COPD, regardless of gender and race.

Information sources: Literature databases: PubMed, EMBASE, CENTRAL, China Biomedical Literature Database, Chinese National Knowledge Infrastructure, Wanfang Data, and VIP Trial registry: Clinicaltrials.gov, and Chinese Clinical Trial Registry. Source of grey literature: reference lists of relevant reviews.

Main outcome(s): The primary outcome will be the number or rate of acute exacerbations.

Additional outcome(s): TCM symptom score, modified British Medical Research Council (MRC) rating, cat score, 6-minute walk distance (6MWD); Forced expiratory volume in one second (FEV1) or % of the expected value, FEV1 / FVC, adverse reaction.

Quality assessment / Risk of bias analysis: A new tool for assessing the risk of bias in randomized trials, known as“RoB 2,”is available for risk of bias evaluation in systematic reviews (Sterne 2019). Evaluation items are as follows: random distribution method; The allocation scheme will be unavailable to the participants; Blinding the subjects and experimenters; Blinding outcome evaluators; Integrity of result data; Selective reporting of research results; Other sources of bias.

Strategy of data synthesis: Revman 5.3 provided by Cochrane Collaboration Network will be used to conduct data analysis. The effect statistics of counting data are expressed by relative risk (RR); For measurement data, if the measurement units are the same and the mean difference is small between different studies, it is expressed by mean difference - force (MD), and if the measurement units are different and the mean difference is too large, it will be expressed by standardized mean difference (SMD); The combined results will

be represented by effect value and 95% confidence interval (CI).

Subgroup analysis: According to the different treatment schemes of Western medicine, the included studies will be analyzed into subgroups, which will be divided into the following groups: Shenqi Bufei Decoction + routine treatment vs routine treatment, Shenqi Bufei Decoction + salmeterol ticasone powder inhaler vs salmeterol ticasone powder inhaler, Shenqi Bufei Decoction + tiotropium bromide powder inhaler vs tiotropium bromide powder inhaler Shenqi Bufei Decoction + theophylline vs theophylline, Shenqi Bufei Decoction vs placebo, etc. According to the age classification, subgroup analysis will be conducted for the included studies, which were divided into ≤ 18 years old, 18-60 years old and > 60 years old.

Sensitivity analysis: Sensitivity analysis will be performed by excluding studies with high risk of bias and changing the statistical model.

Country(ies) involved: China.

Keywords: shenqi bufei decoction, stable chronic obstructive pulmonary disease, protocol, systematic review, meta-analysis.

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