INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Combination of Jinshuibao Capsules and Conventional Pharmaceutical Treatments for Patients with Stable Chronic Obstructive Pulmonary Disease: A Systematic Review and a Meta-Analysis

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Review question / Objective: Jinshuibao capsules are derived from Cordyceps, and they have been widely used in the treatment of different diseases. They have also been utilized in the treatment of respiratory diseases, while their effects on patients with stable chronic obstructive pulmonary disease (COPD) have remained elusive. The present study aimed to compare the efficacy of Jinshuibao capsules plus conventional pharmaceutical treatments (CPT) versus CPT alone for patients with stable COPD.

Information sources: It was attempted to conduct a systematic review and a meta-analysis based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. In addition, PubMed, EMBASE, Cochrane Library, Web of Science, China Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, VIP Information Resource Integration Service Platform (CQVIP), and China Biomedicine (SinoMed) databases were searched from inception until September 30, 2021. Google Scholar and the China Clinical Trial Registry were also searched for retrieving missing data. In emergency conditions, we contacted the corresponding authors of retrieved studies for collection of additional data.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 October 2021 and was last updated on 30 October 2021 (registration number INPLASY2021100117).

INTRODUCTION

Review question / Objective: Jinshuibao capsules are derived from Cordyceps, and they have been widely used in the treatment of different diseases. They have also been utilized in the treatment of respiratory diseases, while their effects on patients with stable chronic obstructive pulmonary disease (COPD) have remained elusive. The present study aimed to compare the efficacy of Jinshuibao

capsules plus conventional pharmaceutical treatments (CPT) versus CPT alone for patients with stable COPD.

Condition being studied: Cochrane Library, Web of Science, EMBASE, PubMed, China Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, VIP Information Resource Integration Service Platform (CQVIP), and China Biomedicine (SinoMed) databases were searched from inception until September 30, 2021 to find out randomized clinical trials (RCTs) that have evaluated the effects of Jinshuibao capsules plus CPT versus CPT alone on patients with stable COPD. The primary outcomes included the percentage of forced expiratory volume in 1 second (FEV1%), ratio of FEV1 to forced vital capacity (FVC) (FEV1/FVC), FEV1, and FVC. Secondary outcomes included partial pressure of oxygen (PaO2) level, partial pressure of carbon dioxide (PaCO2) level, the number of CD3+ T cells in peripheral blood samples, the ratio of CD4+/CD8+ T cells in peripheral blood samples (CD4+/CD8+), the ratio of regulatory T cells/T helper 17 cells in peripheral blood samples (Th17/Treg), interleukin-8 (IL-8) level, tumor necrosis factor-α (TNF-α) level, and superoxide dismutase (SOD) level. The data were independently extracted by two researchers.

METHODS

Participant or population: Patients with stable chronic obstructive pulmonary disease (COPD).

Intervention: Jinshuibao capsules.

Comparator: Conventional pharmaceutical treatments (CPT).

Study designs to be included: RCTs.

Eligibility criteria: 1) Studies that were published as RCTs; 2) RCTs that enrolled patients who were diagnosed with stable COPD according to the GOLD guidelines; 3) RCTs that included control group (i.e., patents who received CPT) and experimental group (i.e., patients who

received Jinshuibao capsules combined with CPT); 4) RCTs that included one or more of the following outcomes: percentage of FEV1 (FEV1%), FEV1/FVC ratio, FEV1, FVC, partial pressure of oxygen (PaO2) level, partial pressure of carbon dioxide (PaCO2) level, the number of CD3+ T cells in peripheral blood samples, the ratio of CD4+/CD8+ T cells in peripheral blood samples (CD4+/CD8+), the ratio of regulatory T cells/T helper 17 cells in peripheral blood samples (Th17/Treg), interleukin-8 (IL-8) level, tumor necrosis factor-α (TNF-α) level, and superoxide dismutase (SOD) level.

Information sources: It was attempted to conduct a systematic review and a meta-analysis based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement. In addition, PubMed, EMBASE, Cochrane Library, Web of Science, China Knowledge Infrastructure (CNKI), Wanfang Data Knowledge Service Platform, VIP Information Resource Integration Service Platform (CQVIP), and China Biomedicine (SinoMed) databases were searched from inception until September 30, 2021. Google Scholar and the China Clinical Trial Registry were also searched for retrieving missing data. In emergency conditions, we contacted the corresponding authors of retrieved studies for collection of additional data.

Main outcome(s): The primary outcomes included the percentage of forced expiratory volume in 1 second (FEV1%), ratio of FEV1 to forced vital capacity (FVC) (FEV1/FVC), FEV1, and FVC.

Additional outcome(s): Secondary outcomes included partial pressure of oxygen (PaO2) level, partial pressure of carbon dioxide (PaCO2) level, the number of CD3+ T cells in peripheral blood samples, the ratio of CD4+/CD8+ T cells in peripheral blood samples (CD4+/CD8+), the ratio of regulatory T cells/T helper 17 cells in peripheral blood samples (Th17/Treg), interleukin-8 (IL-8) level, tumor necrosis factor-α (TNF-α) level, and superoxide dismutase (SOD)level.

Quality assessment / Risk of bias analysis:
The risk of bias was assessed by two reviewers using the Cochrane Collaboration's tool. The assessment included random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting, and other sources of bias. Each trial was evaluated at "high-", "low-", or "unclear-" risk of bias.

Strategy of data synthesis: Statistical analysis was performed using the RevMan 5.3 (Cochrane, London, UK) software. The effect size was measured as a relative risk (RR) and 95% CI (95% CI) for dichotomous data. For continuous data, mean difference (MD) and 95% CI were utilized to represent the effect size. We used the I2 statistic to test the heterogeneity among the included studies. If I2 ≥ 50% represented a substantial heterogeneity, thus, the random-effects model was used to perform the analysis; otherwise, the fixed-effects model was utilized.

Subgroup analysis: Subgroup analysis was used to identify any source of heterogeneity.Statistical analysis was performed using the RevMan 5.3 (Cochrane, London, UK) software.

Sensitivity analysis: The sensitivity analysis was conducted to explore whether the results are sensitive to exclusion of low-quality studies.

Country(ies) involved: China.

Keywords: COPD; Jinshuibao capsules; meta-analysis.

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