

INPLASY PROTOCOL

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Corresponding author:
Jian-Ping Liu

jianping_l@hotmail.com

Author Affiliation:
Beijing University of Chinese
Medicine

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**Review Stage at time of this
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Chinese patent herbal medicine Shufeng Jiedu capsule as an adjuvant therapy for community-acquired pneumonia: a protocol of systematic review and meta-analysis of randomized clinical trials

Zhang, X¹; Xia, R²; Li, X³; Dai, M⁴; Hu, X⁵; Willcox, M⁶; Fei, Y⁷; Moore, M⁸; Liu, JP⁹.

Review question / Objective: As adjuvant therapy, are the Shufeng Jiedu (SFJD) capsule effective or safe for patients with community-acquired pneumonia (CAP)?

Condition being studied: This systematic review is going to evaluate the effectiveness and safety of SFJD capsule in CAP treatment.

Information sources: We will identify trials from the following databases: Pubmed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Library, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Chinese biomedical literature database (CBM) via Sinomed and Wanfang database. We will also conduct a search of ClinicalTrials.gov (<http://clinicaltrials.gov>), the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/) and Chinese Clinical Trial Registry (<http://www.chictr.org.cn/index.aspx>) to identify unpublished trials. We will search all databases from their inception to June 2020 and we will not impose any restriction on the language of publication.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 June 2020 and was last updated on 27 June 2020 (registration number INPLASY202060102).

INTRODUCTION

Review question / Objective: As adjuvant therapy, are the Shufeng Jiedu (SFJD)

capsule effective or safe for patients with community-acquired pneumonia (CAP)?

Condition being studied: This systematic review is going to evaluate the

effectiveness and safety of SFJD capsule in CAP treatment.

METHODS

Search strategy: Search strategy for PubMed: (((Shufengjiedu[Title/Abstract]) OR Shu Feng Jie Du[Title/Abstract]) OR Shu-Feng-Jie-Du[Title/Abstract]) OR Shufeng Jiedu[Title/Abstract] Search strategy for China National Knowledge Infrastructure (CNKI):SU='疏风解毒' OR AB='疏风解毒.'

Participant or population: Patients with an admitting diagnosis of community-acquired pneumonia (CAP), regardless of age, race or origins.

Intervention: SFJD capsule combine with conventional interventions such as antibiotic therapy, corticosteroids, physiotherapy or other regular treatment.

Comparator: Antibiotic therapy, corticosteroids, physiotherapy, other regular treatment, placebo, or no treatment.

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

Eligibility criteria: Studies: randomized controlled trials (RCTs). Participants: patients with an admitting diagnosis of CAP, regardless of age, race or origins. Intervention: SFJD capsule combine with conventional interventions such as antibiotic therapy, corticosteroids, physiotherapy or other regular treatment. Comparison: antibiotic therapy, corticosteroids, physiotherapy, other regular treatment, placebo, or no treatment; Outcomes including primary outcomes- resolution time of clinical symptoms, like fever, cough, expectoration, lung rale, etc.; Secondary outcomes- all-cause mortality, proportion of patients who had improved chest radiograph, length of stay in hospital, duration and dosage of antibiotics use, treatment compliance, pathogen positive/negative rate, infection-

related indices such as leucocyte (WBC), C-reactive protein (CRP), procalcitonin (PCT), incidence of complications due to CAP, quality of life and adverse events (unintended symptoms or signs, such as loss of function due to de-conditioning, hospital-acquired infections, intravascular-device associated complications, antibiotic-related side effects and corticosteroid-related side effects, etc.).

Information sources: We will identify trials from the following databases: Pubmed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials (CENTRAL) via the Cochrane Library, China National Knowledge Infrastructure (CNKI), Chinese Scientific Journal Database (VIP), Chinese biomedical literature database (CBM) via Sinomed and Wanfang database. We will also conduct a search of ClinicalTrials.gov (<http://clinicaltrials.gov>), the World Health Organization (WHO) International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/) and Chinese Clinical Trial Registry (<http://www.chictr.org.cn/index.aspx>) to identify unpublished trials. We will search all databases from their inception to June 2020 and we will not impose any restriction on the language of publication.

Main outcome(s): Resolution time of clinical symptoms, like fever, cough, expectoration, lung rale, etc.

Additional outcome(s): All-cause mortality, proportion of patients who had improved chest radiograph, length of stay in hospital, duration and dosage of antibiotics use, treatment compliance, pathogen positive/negative rate, infection-related indices such as leucocyte (WBC), C-reactive protein (CRP), procalcitonin (PCT), incidence of complications due to CAP, quality of life and adverse events (unintended symptoms or signs, such as loss of function due to de-conditioning, hospital-acquired infections, intravascular-device associated complications, antibiotic-related side effects and corticosteroid-related side effects, etc.).

Quality assessment / Risk of bias analysis:

Two review authors will independently assess the risk of bias for each study using Risk of Bias 2. We will resolve any disagreements by discussion. We will assess the risk of bias according to the following domains: Bias arising from the randomization process; Bias due to deviations from intended interventions; Bias due to missing outcome data; Bias in measurement of the outcome; Bias in selection of the reported result; Overall bias. We will assess each potential source of bias as “probably no”, “no”, “probably yes”, “yes”, “not applicable” and “no information”. When considering treatment effects, we will take into account the risk of bias for the studies that contributed to that outcome.

Strategy of data synthesis: We will estimate effect size using risk ratio (RR) for dichotomous data and mean difference (MD) or standardized mean difference (SMD) for continuous data. We will enter data presented as a scale with a consistent direction of effect. We do not anticipate “censored” patients, but if available we will include them in the analysis. We will undertake a meta-analysis only where this is meaningful, that is, if the treatments, participants and underlying clinical question are similar enough (homogeneous) for pooling. We will use the GRADE to assess the quality and confidence of the body of evidence for primary outcomes.

Subgroup analysis: Subgroup analyses will be used to explore possible sources of heterogeneity, based on the following: the severity of CAP (outpatient care, inpatient admission, or Intensive Care Unit (ICU) admission); pathogen (bacterial, viral, fungal or atypical CAP); patient age (≤ 5 years old, 5-65 years old, ≥ 65 years old).

Sensibility analysis: Sensitivity analysis will be performed to challenge the robustness of the results when there are clinically meaningful differences in primary outcomes considering: multi-center versus single center; risk of bias (by omitting

studies that are judged to be at high risk of bias); re-analyses studies with missing data using a reasonable range of missing values.

Language: No restriction on the language of publication.

Country(ies) involved: China, UK.

Keywords: community-acquired pneumonia; CAP; Shufeng Jiedu; systematic review; traditional Chinese medicine.

Contributions of each author:

Author 1 - Xiao-wen Zhang.

Author 2 - Ru-yu Xia.

Author 3 - Xun Li.

Author 4 - Meng-yuan Dai.

Author 5 - Xiao-yang Hu.

Author 6 - Merlin Willcox.

Author 7 - Yu-tong Fei.

Author 8 - Michael Moore.

Author 9 - Jian-ping Liu.

Conflicts of interest: The authors declare that they have the following possible conflicts of interest. However, these conflicts of interest do not actually influence the design, analyses, and the reporting of this study. This work is supported by the project investigating the use of Chinese herbal medicine for the treatment of chronic obstructive pulmonary disease. The project is part of the “UK-China collaboration to tackle antimicrobial resistance”, funded by the UK and Chinese governments.