INPLASY PROTOCOL

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Review Stage at time of this submission: **The review has not yet started.**

Conflicts of interest:
All authors declare that they have no conflict of interest.

The clinical efficacy of traditional Chinese medicine in the treatment of rheumatoid arthritis with interstitial lung disease: A protocol of systematic review and meta-analysis

Liu, Z[1]; Shen, J[2]; Shen, Z[3]; He, D[4].

Review question / Objective: **P: diagnosed as rheumatoid arthritis with interstitial lung disease; I: traditional Chinese medicine; C: other type treatment; O: Lung function, number of swelling joints, number of painful joints, duration of morning stiffness, VAS score, adverse effects, quality of life, ESR, CRP, rheumatoid factor and safety were assessed; S: comparative design were included.**
Condition being studied: **Rheumatoid arthritis with interstitial lung disease.**
Information sources: **We will perform literature searches using the following electronic bibliographic databases from their inception onwards to the August 2020: MEDLINE, Springer, Web of Science, PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, Evidence Based Medicine Reviews, VIP, and CNKI. We will not establish any limitations to language and publication status. The following electronic databases were searched from their inception dates through August 2020.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 August 2020 and was last updated on 26 August 2020 (registration number INPLASY202080108).

INTRODUCTION

Review question / Objective: **P: diagnosed as rheumatoid arthritis with interstitial lung disease; I: traditional Chinese medicine; C: other type treatment; O: Lung function, number of swelling joints, number of painful joints, duration of morning stiffness, VAS score, adverse effects, quality of life, ESR, CRP, rheumatoid factor and safety were assessed; S: comparative design were included.**

Condition being studied: Rheumatoid arthritis with interstitial lung disease.

METHODS

Participant or population: P: diagnosed as rheumatoid arthritis with interstitial lung disease.

Intervention: Traditional Chinese medicine.

Comparator: Other type treatment.

Study designs to be included: Comparative design.

Eligibility criteria: Patients suffered from RA-ILD will be included without sex, age, course, ethnicity, disease duration or disease severity restrictions.

Information sources: We will perform literature searches using the following electronic bibliographic databases from their inception onwards to the August 2020: MEDLINE, Springer, Web of Science, PubMed, EMBASE, the Cochrane Central Register of Controlled Trials, Evidence Based Medicine Reviews, VIP, and CNKI. We will not establish any limitations to language and publication status. The following electronic databases were searched from their inception dates through August 2020.

Main outcome(s): (1) Lung function. (2) The number of swelling joints affected by RA. (3) The number of painful joints affected by RA. (4) The duration of morning stiffness.

Additional outcome(s): (1) Pain visual analog scale (VAS) score. (2) Physician VAS score. (3) Adverse effects. (4) Quality of life. (5) Erythrocyte sedimentation rate. (6) C reactive protein. (7) Rheumatoid factor. (8) Safety.

Quality assessment / Risk of bias analysis: The Cochrane risk of bias tool, which is recommended by the Cochrane Reviewer's Handbook 5.0.24, will be used to evaluate the quality of the included studies. Two independent reviewers will evaluate the quality of selected articles from the following 5 aspects: selection bias (random sequence generation or allocation concealment), performance bias and detection bias (blinding), attrition bias (incomplete outcome data), reporting bias (selective outcome reporting), and other biases. If necessary, we will contact the corresponding author to clarify issues. The result of the consistency evaluation will be presented with Kappa statistics, Kappa value <0.75 will be considered the consistency have reached. Any disagreements will be resolved through discussion or consultation.

Strategy of data synthesis: We will undertake RevMan 5.3 software to analyze data and to perform meta-analysis if it is necessary. We will calculate all continuous data using mean difference or standardized mean difference and 95% confidence intervals. As for dichotomous data, we will exert it using risk ratio and 95% CI. The heterogeneity as determined by the Cochran statistics was 50%, we marked it as a considerable level of heterogeneity; otherwise, we considered it to be a good homogeneity. We also assessed clinical heterogeneity. Statistically and clinically homogeneous studies were pooled using a fixed-effects model; otherwise, a random-effects model was used when the heterogeneity was significant. Additionally, subgroup analysis will be operated to explore any possible reasons for the high heterogeneity. Whenever it is possible, we will conduct meta-analysis if at least 3 eligible criteria are fulfilled. Otherwise, meta-analysis will not be carried out if only 1 or 2 studies meet the inclusion criteria. Under such situation, the findings will be presented in a narrative summary. We will perform narrative synthesis if running meta-analysis is inappropriate due to the high heterogeneity. All narrative descriptions will be carried out based on the Guidance on the Conduct of Narrative Synthesis in Systematic Reviews.ZH.

Subgroup analysis: We will preside over subgroup analysis to explore any potential heterogeneity and inconsistency based on the different factors.

Sensibility analysis: We will consider running sensitivity analysis to identify the robustness and stability of merged results by excluding studies with high risk of bias.

Country(ies) involved: China.

Keywords: protocol; systematic review; traditional Chinese medicine; rheumatoid arthritis; interstitial lung disease.

Contributions of each author:
Author 1 - Zhaoyi Liu.
Author 2 - Jie Shen.
Author 3 - Zhouli Shen.
Author 4 - Dongyi He.