

INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effectiveness and safety of Chinese herbal formula combined with western medicine for ankylosing spondylitis: A protocol for systematic review and meta-analysis

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Review question / Objective: This study aims to comprehensively synthesize randomized controlled trial (RCT) of Chinese herbal formulas (CHF) combined with western medicine for the treatment of ankylosing spondylitis (AS) to assess their efficacy and safety.

Condition being studied: Ankylosing spondylitis (AS) is a chronic progressive inflammatory disease of the spine, which mainly invades the sacroiliac joint, spine and large joints near the trunk, leading to fibrous and skeletal ankylosis and deformity, and can cause damage to the eyes, lung, cardiovascular, kidney and other organs. Chinese herbal formulas (CHF) is an important interventions of Traditional Chinese Medicine (TCM), and CHFs combined with western medicine are widely used in clinical practice to treat AS.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 May 2021 and was last updated on 25 May 2021 (registration number INPLASY202150089).

INTRODUCTION

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METHODS

Participant or population: The participants should be diagnosed with AS by using clearly defined or internationally recognized criteria.

Intervention: CHFs combined with western medicine should be applied in the treatment group.

Comparator: The same western medicine should be used for the control group.

Study designs to be included: We will include RCTs of CHFs combined with western medicine in the treatment of AS, which should evaluate at least one primary outcome.

Eligibility criteria: Only Chinese and English literatures will be included in this study regardless of blind and publication type.

Information sources: RCTs of CHFs combined with western medicines for AS will be retrieved in the following databases: PubMed, EMBASE, Cochrane Central Register of Controlled Trials, Web of Science, Chinese Biomedical Literatures Database (CBM), China National Knowledge Infrastructure (CNKI), Wang Fang Database (WF), Chinese Scientific Journal Database (VIP).

Main outcome(s): The outcome measures we focused on included clinical effectiveness rate, TCM syndrome score, TCM symptom score, Bath ankylosing spondylitis disease activity index (BASDAI), functional ability that measured by the Bath Ankylosing Spondylitis Functional Index (BASFI), mobility that measured by the Bath Ankylosing Spondylitis Metrology Index

(BASMI), Chest expansion, nocturnal spinal pain, adverse reactions, erythrocyte sedimentation rate (ESR) and C protein response (CRP).

Quality assessment / Risk of bias analysis: The risk of bias of RCTs included will be evaluated on the basis of the risk of bias tool described in the Cochrane Handbook for Systematic Reviews of Interventions. Furthermore, Two reviewers will independently use the modified Jadad scale to assess the quality of the RCTs included.

Strategy of data synthesis: RevMan V.5.3.0 software will be used for meta-analysis. Binary variables will be expressed using the risk ratio (RR) with 95% confidence interval (CI) and continuous variables by the weighted mean difference(WMD) with 95% CI. The Q-test and I² values will be applied to measure the inter-study heterogeneity. When the p-value of Q-test > 0.1 and I² < 50%, heterogeneity is acceptable and a fixed effects model will be applied. If p-value of Q-test < 0.1 and I² > 50%, heterogeneity is significant and subgroup analysis will be developed to investigate the possible sources according to the characteristics of study, types of intervention and controls, different outcome measurements and study quality, if still unable to find, we will use random effect model to estimate or descriptive analysis.

Subgroup analysis: When heterogeneity is significant, subgroup analysis will be developed to investigate the possible sources according to the characteristics of study, types of intervention and controls, different outcome measurements and study quality.

Sensitivity analysis: Sensitivity analysis is performed by varying certain important factors that may affect the results such as inclusion criteria, study quality, statistical methods and effect size, etc., and then we will perform the analysis to compare with the original results.

Country(ies) involved: China.

Keywords: Chinese herbal formula;
ankylosing spondylitis; meta-analysis;
systematic review.

Contributions of each author:

Author 1 - Miao Liu.

Author 2 - Xiaolei Deng.

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