

INPLASY PROTOCOL

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None declared.

Therapeutic effects of traditional Chinese medicine fumigating plus Yang-He decoction for patients with ankylosing spondylitis: A systematic review and network meta-analysis

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Review question / Objective: To assess the therapeutic effects of combined TCMF with YHD for AS patients.

Condition being studied: Traditional Chinese medicine fumigating (TCMF) and Yang-He decoction (YHD) are widely used for ankylosing spondylitis (AS), whether combined used TCMF and YHD provides superior therapeutic effects for AS remained unclear.

Eligibility criteria: (1) Patients: adult patients diagnosed with AS; (2) Treatments: TCMF plus YHD, TCMF, YHD, and WM; (3) Outcomes: the primary endpoint was effective rate, and the secondary endpoints including Visual Analogue Scale (VAS) score, Schober test (ST), thoracic expansion (TE), finger-floor distance (FFD), pillow-wall distance (PWD), spinal column activity (SCA), morning stiffness time (MST), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP); and (4) Study design: the study had to have RCT design.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 April 2023 and was last updated on 20 April 2023 (registration number INPLASY202340074).

INTRODUCTION

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Condition being studied: Traditional Chinese medicine fumigating (TCMF) and Yang-He decoction (YHD) are widely used for ankylosing spondylitis (AS), whether combined used TCMF and YHD provides superior therapeutic effects for AS remained unclear.

METHODS

Search strategy: “Traditional Chinese medicine fumigating” OR “Yang-He decoction” AND “ankylosing spondylitis”.

Participant or population: Adult patients diagnosed with AS.

Intervention: TCMF plus YHD, TCMF, YHD.

Comparator: WM.

Study designs to be included: The study had to have RCT design.

Eligibility criteria: (1) Patients: adult patients diagnosed with AS; (2) Treatments: TCMF plus YHD, TCMF, YHD, and WM; (3) Outcomes: the primary endpoint was effective rate, and the secondary endpoints including Visual Analogue Scale (VAS) score, Schober test (ST), thoracic expansion (TE), finger-floor distance (FFD), pillow-wall distance (PWD), spinal column activity (SCA), morning stiffness time (MST), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP); and (4) Study design: the study had to have RCT design.

Information sources: We systematically searched PubMed, EmBase, Cochrane library, China National Knowledge Infrastructure, Wanfang, and VIP to identify potential included trials throughout April 2023, and using “Traditional Chinese medicine fumigating” OR “Yang-He decoction” AND “ankylosing spondylitis” as search terms. The websites of ClinicalTrials.gov (US NIH) was also searched to identify trials have already completed but not yet published. The reference lists of relevant review and trials were also manually searched to identify any new eligible trials.

Main outcome(s): Effective rate.

Additional outcome(s): Visual Analogue Scale (VAS) score, Schober test (ST), thoracic expansion (TE), finger-floor

distance (FFD), pillow-wall distance (PWD), spinal column activity (SCA), morning stiffness time (MST), Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), erythrocyte sedimentation rate (ESR), and C-reactive protein (CRP).

Quality assessment / Risk of bias analysis: Risk of bias described by the Cochrane Collaboration, which including random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias.

Strategy of data synthesis: The indirect and mixed comparisons in network meta-analysis was applied to compare and rank the various treatments for AS, and the differences between direct and indirect estimates for a specific comparison was applied the loop-specific approach. The consistency in network was evaluated by the design-by treatment interaction inconsistency model. The surface under the cumulative ranking (SUCRA) probabilities were used to compare and rank the treatments for AS in effective rate. For secondary endpoints, the pooled results were calculated using the random-effects model, which could considering underlying varies across included trials.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Language restriction: English and Chinese.

Country(ies) involved: China.

Keywords: traditional Chinese medicine fumigating; Yang-He decoction; ankylosing spondylitis; systematic review; network meta-analysis.

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