

Efficacy and safety of Yiqi Yangyin decoction combined western medicine in treating Systemic Lupus Erythematosus: a Meta-Analysis

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ADMINISTRATIVE INFORMATION**Support** - Medical Development Fund Project of Heilongjiang Province.**Review Stage at time of this submission** - Data extraction.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY2023110103**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 November 2023 and was last updated on 27 November 2023.**INTRODUCTION**

Review question / Objective Systemic lupus erythematosus (SLE) is a diffuse connective tissue disease characterized by autoimmune inflammation. China has the second highest incidence of SLE in the world, with approximately one million SLE patients, making it one of the most prevalent rheumatic diseases. According to traditional Chinese medicine literature, SLE falls under the category of Yin-yang Toxins, and Yiqi Yangyin Decoction is a commonly utilized herbal decoction for managing SLE associated with QiYin futile effort.

Condition being studied Systemic lupus erythematosus (SLE) is a diffuse connective tissue disease characterized by autoimmune inflammation. China has the second highest incidence of SLE in the world, with approximately one million SLE patients, making it one of the most prevalent rheumatic diseases. According to traditional Chinese medicine literature, SLE falls under the category of Yin-yang Toxins, and Yiqi

Yangyin Decoction is a commonly utilized herbal decoction for managing SLE associated with QiYin futile effort.

METHODS

Search strategy (“系统性红斑狼疮”OR“狼疮”OR“SLE” OR“Systemic lupus Erythematosus”) AND (“益气养阴”OR“Yiqi Yangyin”) .

Participant or population SLE Patients in China.

Intervention Patients in the observation group, take Yiqi Yangyin Decoction combined Western medicine.

Comparator Patients in the control group, take Western medicine only.

Study designs to be included A clinical trial investigating the integration of the Yiqi Yangyin method into the treatment regimen for systemic lupus erythematosus (including randomized

controlled trials and other study designs) was conducted. Following a systematic literature review, data extraction, and assessment of methodological quality in the included studies, a meta-analysis was performed using Review Manager 5.3 software.

Eligibility criteria Incorporate into the standard: 1. All included literature comprises clinical randomized controlled trials involving patients diagnosed with systemic lupus erythematosus. 2. The intervention group received a combination treatment of Yiqi Yangyin decoction and Western medicine, while the control group received monotherapy with Western medicine alone. 3. Participants met the SLE classification criteria established by the American College of Rheumatology (ACR). Exclusion criteria: 1. Duplicate studies; 2. Studies lacking extractable valid data; 3. Studies presenting significant controversial.

Information sources PubMed, Medline, Embase, Cochrane Library, Web of science, CBM, Wangfang, CNKI and VIP.

Main outcome(s) The retrieval period commences upon the establishment of the database and concludes on November 21, 2023. A total of 281 relevant literature sources were identified, including PubMed (n=1), Medline (n=0), Embase (n=0), Cochrane (n=0), Web of Science (n=0), Wanfang Database (n=91), CNKI Database (n=74), VIP Database (n=69) and CBM Database (n=46). After removing duplicates, a final set of 122 articles was obtained. By screening the titles, keywords, and abstracts for relevance, 35 articles were selected. Finally, after thorough examination of the full texts and exclusion of further unrelated studies, a total of 19 articles were included for meta-analysis.

Data management The literature included in this study was evaluated for quality using the bias risk assessment tool recommended by the Cochrane Handbook for Systematic Reviews-5.1 edition.

Quality assessment / Risk of bias analysis 11 studies utilized the random number table method, while 5 studies employed randomization without providing specific details. 3 studies allocated participants randomly based on hospital admission numbers, outpatient numbers, or competitive entry. 19 studies did not provide descriptions of allocation or blinding procedures for interventions. 18 studies did not implement blinding for outcome assessment, whereas 2 studies utilized fixed personnel to conduct blinded outcome

evaluations. 19 studies had complete outcome data. 2 studies exhibited selective reporting and were excluded from the analysis. 4 studies demonstrated bias in clinical efficacy design.

Strategy of data synthesis Binary outcomes were calculated as relative risk (RR) and 95% CI, odds ratio (OR) and 95% CI. Continuous outcomes were calculated as weighted mean difference (MD) along with 95% confidence intervals (95% CIs) or standard mean difference (SMD) along with 95% confidence intervals (95% CIs) for effect sizes.

Subgroup analysis ① Clinical efficacy ② Traditional Chinese Medicine symptom score ③ White blood cells ④ Erythrocyte sedimentation rate (ESR) ⑤ Antinuclear antibodies (ANA) ⑥ ds-DNA antibody test ⑦ IgG antibodies ⑧ C3 complement component levels ⑨ Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) ⑩ Adverse reactions.

Sensitivity analysis In the presence of heterogeneity in the combined findings, a systematic exclusion process will be employed, starting with the removal of one literature at a time. Subsequently, a meta-analysis will be conducted on the remaining studies (n-1). By closely monitoring alterations in the aggregated outcomes, we can evaluate whether specific studies exerted significant influence on the original meta-analysis results.

Language restriction Chinese.

Country(ies) involved China.

Other relevant information Submit an article to a Chinese academic journal.

Keywords Yiqi Yangyin Decoction; Systemic lupus Erythematosus; Chinese-Western Medicine Treatment; Meta-Analysis.

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