

INPLASY

Efficacy and safety of Yiqi Yangyin decoction 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.

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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 05 January 2024.

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.

Rationale The incidence of SLE in China is the second highest in the world, with about 1 million patients. The SLE patients faced by doctors are characterized by serious underlying diseases and high complication rate. In recent years, many scholars have discussed the value of traditional

medicine in the diagnosis and treatment of SLE, triggering multidisciplinary discussions, focusing on the drug regimen and efficacy of combined Chinese and western medicine in the treatment of SLE and Lupus Nephritis.

Condition being studied Yiqi-yangyin prescription was retrieved from the Chinese Journal of Integrated Traditional and Western Medicine, 1983, and its addition and subtraction formula is often used by rheumatologists in the treatment of SLE. Currently, there is no meta-analysis.

METHODS

Search strategy The Chinese search terms were "Systemic Lupus Erythematosus", "Lupus", "qi nourishing Yin", and the English search terms were "systemic lupus erythematosus", "SLE", "lupus", and "Yiqi Yangyin".

Participant or population SLE Patients in China.

Intervention The experimental group was treated with Yiqi and yin-nourishing prescription combined with Western medicine, and the control group was treated with Western medicine.

Comparator Efficacy, TCM syndrome score, SLEDAI score, ANA negative conversion rate, ds-DNA negative conversion rate, C3 level, 24h urinary protein quantity, glucocorticoid maintenance and safety.

Study designs to be included A total of 328 literatures were retrieved, 128 were obtained after reselection, 41 were retained for reading the title and abstract, and 24 were retained for reading the full text. A total of 1 991 patients were included, including 1 051 in the experimental group and 940 in the control group.

Eligibility criteria Inclusion criteria: 1. RCT study was included, and the subjects were patients meeting the ACR classification criteria for SLE; 2. The experimental group was treated with Yiqi-yangyin prescription combined with western medicine, and the control group was treated with Western medicine; 3. Outcome indicators included: efficacy, TCM syndrome score, SLEDAI score, ANA negative conversion rate, ds-DNA negative conversion rate, C3 level, 24h urinary protein quantity, glucocorticoid maintenance and safety. Exclusion criteria: 1. Repeated studies; 2. Studies that cannot extract valid data.

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

Main outcome(s) Efficacy and safety.

Additional outcome(s) TCM syndrome score, SLEDAI score, ANA negative conversion rate, ds-DNA negative conversion rate, C3 level, 24h urinary protein quantity and glucocorticoid maintenance.

Data management The literature selection and data extraction were carried out by two researchers using EndNote 20.0, Wps Excle and Review Manager 5.4. The preliminary screening and re-screening were eliminated and the differences were discussed and decided. Author, year, region, diagnostic criteria, number of cases, intervention measures, observation period, efficacy evaluation and outcome indicators were extracted.

Quality assessment / Risk of bias analysis

Quality was assessed using the Cochrane Handbook of Systematic Reviews 5.0 bias risk tools, including random assignment, subject and investigator blindness, outcome evaluation blindness, data integrity, selective reporting, and other bias. Each entry is categorized as High, low, Unknown risk.

Strategy of data synthesis Meta-analysis was performed using RevMan 5.4. Binary variables are represented by Odds Ratio (OR) and its 95% Credibility Interval (CI), while continuous variables are represented by Mean Difference (MD) and 95%CI. The different dimensions are expressed in Standardized Mean Difference (SMD) and 95%CI. χ^2 test and I² test were used to analyze heterogeneity. If $P \leq 0.01$ and $I^2 \geq 50\%$, there was heterogeneity, Random effect model was used; otherwise, Fixed effect model was used.

Subgroup analysis The negative conversion rate was analyzed by subgroup: ANA and ds-DNA.

Sensitivity analysis If heterogeneity was obvious, sensitivity analysis was performed using STATA 15.0, the test level $\alpha = 0.05$. The Egger test was applied for publication bias for projects with more than 10 included studies.

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; Lupus Nephritis; Chinese-Western Medicine Treatment; Meta-Analysis.

Dissemination plans Submit an article to a Chinese academic journal.

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