

INPLASY

Efficacy and safety of Shaogan Fuzi decoction combined with Western medicine in the treatment of Rheumatoid Arthritis: a Meta-Analysis

INPLASY2023120105

doi: 10.37766/inplasy2023.12.0105

Received: 28 December 2023

Published: 28 December 2023

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ADMINISTRATIVE INFORMATION

Support - Heilongjiang Province Traditional Chinese Medicine Project (ZHY16-014).

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120105

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 December 2023 and was last updated on 28 December 2023.

INTRODUCTION

Review question / Objective Systematic review of the effectiveness and safety of Shaogan Fuzi Decoction combined with western medicine in the treatment of rheumatoid arthritis.

Condition being studied Shaogan Fuzi Decoction can act on TNF- α , IL-6, VEGF, PTGS2, JUN, PPARG and other targets, regulate signaling pathways such as PI3K-Akt, inhibit lymphocyte proliferation and promote apoptosis, reduce inflammatory response, and thus treat Rheumatoid Arthritis. Shaogan Fuzi Decoction inhibits the proliferation of synovial cells and pannus in RA joints by down-regulating the HIF-Ang-VEGF axis. However, there is still a lack of systematic evidence-based evaluation of the clinical efficacy and safety of Shaogan Fuzi Decoction in the treatment of RA. This study included the RCT of Shaogan Fuzi Decoction combined with western

medicine in the treatment of RA into a meta-analysis to comprehensively evaluate the therapeutic effect and safety, in order to draw true and comprehensive conclusions and provide reference for clinical treatment.

METHODS

Search strategy Search Access Medicine, PubMed, EMBASE, Cochrane Library, Web of Science, CNKI, Wangfang, VIP and CBM, the time range is from the establishment of the database to December 28, 2023, and search for RCT studies of Shaogan Fuzi decoction combined with western medicine in the treatment of RA. Only Chinese or English documents were searched. The search formula for the Chinese database is: (Rheumatoid Arthritis OR Rheumatoid Arthritis OR RA) AND (Shaogan Fuzi OR Ganshao Fuzi OR Paeony, Licorice and Aconite) The search formula for the English database is: (Rheumatoid Arthritis OR RA)

AND (Shaogan Fuzi OR Ganshao Fuzi OR Shaoyao Gancao Fuzi).

Participant or population Rheumatoid arthritis patients.

Intervention The treatment group was treated with Shaogan Fuzi Decoction combined with western medicine, and the control group was treated with western medicine alone.

Comparator Total effective rate, incidence of adverse reactions, TCM syndrome score, DAS28 score, duration of morning stiffness, number of joint tenderness, number of joint swelling, ESR and CRP.

Study designs to be included RCT studies published in English or Chinese were included.

Eligibility criteria Inclusion criteria: ① Include RCT studies published in English or Chinese; ② Patients who meet the 1987 ACR or 2010 ACR/EULAR RA diagnostic criteria [8]; ③ The treatment group was treated with Shaogan Fuzi Decoction combined with western medicine, and the control group was treated alone. Western medicine treatment; ④ At least 1 relevant outcome indicator, including total effective rate, incidence of adverse reactions, TCM syndrome score, DAS28 score, duration of morning stiffness, number of joint tenderness, number of joint swelling, ESR and CRP. Exclusion criteria ① Duplicate data; ② Incomplete or unavailable data.

Information sources Search Access Medicine, PubMed, EMBASE, Cochrane Library, Web of Science, CNKI, Wangfang, VIP and CBM, the time range is from the establishment of the database to December 28, 2023.

Main outcome(s) Total effective rate, incidence of adverse reactions, TCM syndrome score, DAS28 score, duration of morning stiffness, number of joint tenderness, number of joint swelling, ESR and CRP.

Data management Two researchers used EndNote 20.0, Wps Excel, and Review Manager 5.4 to conduct the preliminary screening and re-screening. If there were any disagreements, they were discussed and adjudicated. The author's name, year of publication, region, classification criteria, number of participants, intervention measures, course of treatment, efficacy determination and outcome indicators were extracted.

Quality assessment / Risk of bias analysis The risk of bias tool of Cochrane Manual of Systematic Reviews 5.0 was used for quality evaluation, including random allocation, blinding of subjects and researchers, blinding of outcome evaluation, data completeness, selective reporting, and other biases. Each item is divided into high risk, low risk, unknown risk.

Strategy of data synthesis Analysis was performed using Review Manager 5.4 software. The risk difference (RD) and 95% confidence interval (CI) were calculated for dichotomous data, and the mean difference (MD)/standardized mean difference (SMD) and 95%CI were calculated for continuous data. Use the chi-square test and I² statistic to evaluate heterogeneity. P<0.05 and I²>50% indicate that there is significant heterogeneity in the trial. Use the random effects model. If P>0.05 and I²≤50%, it indicates that there is significant heterogeneity. Homogeneity, using fixed effects model. A funnel plot was drawn to test for publication bias.

Subgroup analysis The risk difference (RD) and 95% confidence interval (CI) were calculated for dichotomous data, and the mean difference (MD)/standardized mean difference (SMD) and 95% CI were calculated for continuous data. Use the chi-square test and I² statistic to evaluate heterogeneity. P50% indicate that there is significant heterogeneity in the trial. Use the random effects model. If P>0.05 and I²≤50%, it indicates that there is significant heterogeneity. Homogeneity, using fixed effects model.

Sensitivity analysis Sensitivity analysis was performed on items with significant heterogeneity test I² greater than 50% and eliminated one by one.

Country(ies) involved China.

Keywords Rheumatoid Arthritis; Shaogan Fuzi Decoction; Systematic Review; Meta-Analysis.

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