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INPLASY

Chinese Patent Medicines as Add-On Therapy for Adults with Systemic Lupus Erythematosus: A Network Meta-Analysis of Randomized Controlled Trials

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Corresponding author:
Ciyan Peng

pengciyan@163.com

Author Affiliation:
Second Xiangya Hospital.

Chen, J; Zhang, Q; Lu, A; Yang, L; Wen, M; Li, S; Peng, C.

ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Data analysis.

Conflicts of interest - The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

INPLASY registration number: INPLASY202680088

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 August 2026 and was last updated on 24 August 2026.

INTRODUCTION

Review question / Objective Study selection was guided by the Population, Intervention, Comparison, Outcome, and Study Design (PICOS) framework (Amir-Behghadami et al., 2020; Page et al., 2021; Swartz et al., 2021). Studies included in this NMA met the following five criteria: Population: Adults (18+ years) with a primary SLE diagnosis, irrespective of sex, ethnicity, region, or nationality, and without comorbidities like lupus nephritis. Diagnostic and treatment guidelines from Chinese (Li et al., 2020), American (ACR), and European (EULAR) rheumatology associations (Van et al., 2018; Aringer et al., 2019) were required. Intervention: Trials utilizing CPMs alongside standard WM, all Western medicines (WM) included in the study were consistent with the standard treatment for systemic lupus erythematosus (SLE). They were glucocorticoid-based and supplemented with similar types of concomitant medications, such as hydroxychloroquine and immunosuppressants. Studies with additional herbal medicines were excluded. Comparison: Control groups receiving WM alone. Outcome: Changes in SLEDAI scores to evaluate CPM's effectiveness in symptom reduction when combined with WM. Study Design: RCTs from peer-reviewed journals, with no language limitations (English or Chinese). Conference abstracts, reviews, and studies with incomplete data were excluded. The most recent and complete version was used when studies had multiple publications. Electronic searches were performed across PubMed, MEDLINE, Scopus, Web of Science, Cochrane, Embase, CNKI, Science and Technology Journal Database, and Wanfang, from database inception to June 2026. PubMed was searched as it comprehensively includes MEDLINE records; MEDLINE was not searched separately to avoid redundancy. Manual searches were also conducted. Attempts were

made to contact authors for missing data, but due to a low response rate, studies with unresolved data discrepancies were excluded.

Condition being studied Diagnostic and treatment protocols for systemic lupus erythematosus (SLE, ICD-10: M32.9) have been established by the American College of Rheumatology (ACR), the European League Against Rheumatic Diseases (EULAR), and the Chinese government . As an autoimmune disease, SLE involves multiple autoantibodies causing damage to organs like the skin, kidneys, joints, and nervous system, with common symptoms including fever, facial rash, joint pain, and edema. Approximately two-thirds of patients are adults aged 16–55 years. Global incidence ranges from 0 to 241 per 100,000 (Asia-Pacific: 2.5–9.9/100,000); in mainland China, it is 30–70/100,000, with female patients showing a standardized mortality ratio of 3.2 and life expectancy of ~30 years . Due to adverse impacts on patient well-being, healthcare utilization, and work capacity, adult SLE has emerged as a critical public health challenge, requiring effective intervention to mitigate socioeconomic burden . Glucocorticoids, immunosuppressants, and biologic agents are the main treatment modalities for SLE. Despite their apparent efficacy, several adverse effects and comorbidities (e.g.,secondary infections, hypertension, osteoporosis, osteonecrosis of the femoral head, peptic ulcer) are of concern because they directly affect the efficacy of treatment and add to medical and economic burdens . Therefore, finding a cost-effective and alternative complementary therapy is an urgent and unmet need.

METHODS

Search strategy Search strategy and selection criteria
Study selection was guided by the Population, Intervention, Comparison, Outcome, and Study Design (PICOS) framework (Amir-Behghadami et al., 2020; Page et al., 2021; Swartz et al., 2021). Studies included in this NMA met the following five criteria: Population: Adults (18+ years) with a primary SLE diagnosis, irrespective of sex, ethnicity, region, or nationality, and without comorbidities like lupus nephritis. Diagnostic and treatment guidelines from Chinese (Li et al., 2020), American (ACR), and European (EULAR) rheumatology associations (Van et al., 2018; Aringer et al., 2019) were required. Intervention: Trials utilizing CPMs alongside standard WM, all Western medicines (WM) included in the study were consistent with the standard treatment for systemic lupus erythematosus (SLE). They were glucocorticoid-based and supplemented with similar types of concomitant medications, such as hydroxychloroquine and immunosuppressants. Studies with additional herbal medicines were excluded. Comparison: Control groups receiving WM alone. Outcome: Changes in SLEDAI scores to evaluate CPM's effectiveness in symptom reduction when combined with WM. Study Design: RCTs from peer-reviewed journals, with no language limitations (English or Chinese). Conference abstracts, reviews, and studies with incomplete data were excluded. The most recent and complete version was used when studies had multiple publications. Electronic searches were performed across PubMed, MEDLINE, Scopus, Web of Science, Cochrane, Embase, CNKI, Science and Technology Journal Database, and Wanfang, from database inception to June 2026. PubMed was searched as it comprehensively includes MEDLINE records; MEDLINE was not searched separately to avoid redundancy. Manual searches were also conducted. Attempts were made to contact authors for missing data, but due to a low response rate, studies with unresolved data discrepancies were excluded.

Participant or population Search strategy and selection criteria
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Intervention Trials utilizing CPMs alongside standard WM, all Western medicines (WM) included in the study were consistent with the standard treatment for systemic lupus erythematosus (SLE).

Comparator Control groups receiving WM alone. Outcome: Changes in SLEDAI scores to evaluate CPM's effectiveness in symptom reduction when combined with WM.

Study designs to be included Study Design: RCTs from peer-reviewed journals, with no language limitations (English or Chinese).

Eligibility criteria Study selection was guided by the Population, Intervention, Comparison, Outcome, and Study Design (PICOS) framework (Amir-Behghadami et al., 2020; Page et al., 2021; Swartz et al., 2021). Studies included in this NMA met the following five criteria: Population: Adults (18+ years) with a primary SLE diagnosis, irrespective of sex, ethnicity, region, or nationality, and without comorbidities like lupus nephritis. Diagnostic and treatment guidelines from Chinese (Li et al., 2020), American (ACR), and European (EULAR) rheumatology associations (Van et al., 2018; Aringer et al., 2019) were required. Intervention: Trials utilizing CPMs alongside standard WM, all Western medicines (WM) included in the study were consistent with the standard treatment for systemic lupus erythematosus (SLE). They were glucocorticoid-based and supplemented with similar types of concomitant medications, such as hydroxychloroquine and immunosuppressants. Studies with additional herbal medicines were excluded. Comparison: Control groups receiving WM alone. Outcome: Changes in SLEDAI scores to evaluate CPM's effectiveness in symptom reduction when combined with WM. Study Design: RCTs from peer-reviewed journals, with no language limitations (English or Chinese). Conference abstracts, reviews, and studies with incomplete data were excluded. The most recent and complete version was used when studies had multiple publications. Electronic searches were performed across PubMed, MEDLINE, Scopus, Web of Science, Cochrane, Embase, CNKI, Science and Technology Journal Database, and Wanfang, from database inception to June 2026. PubMed was searched as it comprehensively includes MEDLINE records; MEDLINE was not searched separately to avoid redundancy. Manual searches were also conducted. Attempts were made to contact authors for missing data, but due to a low response rate, studies with unresolved data discrepancies were excluded.

Information sources PubMed was searched as it comprehensively includes MEDLINE records; MEDLINE was not searched separately to avoid redundancy. Manual searches were also conducted. Attempts were made to contact authors for missing data, but due to a low response rate, studies with unresolved data discrepancies were excluded.A comprehensive set of search terms was applied to retrieve all potentially relevant studies on CPMs combined with WM for SLE treatment.

Main outcome(s) The primary endpoints of this study were to determine: (i) the comparative total effective rate (TER) across treatments; and (ii) the modification of SLE disease activity, as quantified by the SLEDAI score, following intervention. Secondary endpoints consisted of changes in serum immunoglobulin concentrations (IgA, IgG, IgM). In instances where multiple assessment methods were reported, preference was given to those utilizing objective clinical evaluations.

Quality assessment / Risk of bias analysis Data extraction was conducted by two reviewers (MW, AJL) independently. The following information was collected for each article using a standardized form for data extraction: (1) study details (e.g.,), sample size, average participant age and illness duration, sex distribution, and participant characteristics at baseline); (2) specific information on interventions (e.g.,), dosage, and regimen of CPMs); (3) methodological aspects, including risk of bias assessment and diagnostic tools; (4) effects on SLE symptoms (e.g.,), post-intervention total score for SLE symptoms), with a third researcher available to resolve disagreements.MW and AJL assessed bias (RoB2, Sterne et al., 2019): randomization, intervention deviations, missing data, outcome measurement, and selective reporting (Sterne et al., 2019). This tool evaluated five key areas: bias arising from randomization, deviations from planned interventions, incomplete

outcome data, outcome measurement, and selective reporting. Studies were then categorized as having "low," "some," or "high" risk of bias. Separately, CJL and XHL, acting as independent reviewers, appraised the certainty of evidence using the GRADE framework.

Strategy of data synthesis MW and AJL assessed bias (RoB2, Sterne et al., 2019): randomization, intervention deviations, missing data, outcome measurement, and selective reporting (Sterne et al., 2019). This tool evaluated five key areas: bias arising from randomization, deviations from planned interventions, incomplete outcome data, outcome measurement, and selective reporting. Studies were then categorized as having "low," "some," or "high" risk of bias. Separately, CJL and XHL, acting as independent reviewers, appraised the certainty of evidence using the GRADE framework.

Subgroup analysis No.

Sensitivity analysis No.

Country(ies) involved China.

Keywords Chinese patent medicines; systemic lupus erythematosus; add-on therapy; network meta-analysis; randomized controlled trials.

Other relevant information Availability of data and materials - All materials and dataa can be obtained from the corresponding authors upon reasonable request.

Contributions of each author

Author 1 - Jing chen - Draft articles.
Email: chenjing10121989@163.com
Author 2 - Qin Zhang.
Author 3 - Aijuan Lu.
Author 4 - Lei Yang.
Author 5 - Min Wen.
Author 6 - Sini Li.
Author 7 - Ciyan Peng.

JC and CYP conceived and designed the NMA. QZ, MW, AJL, CJL, SNL, XHL, and SNL conducted the NMA. MW and AJL evaluated the quality of included studies. CJL, SNL, XHL, SNL, and CYP analyzed the study data. MW, JC, and CYP wrote the manuscript. All authors approved the final version of the manuscript.