INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Efficacy and safety of Chinese herbal medicine in the treatment of chronic pruritus: a systematic review and meta-analysis

Wang, J[1]; Yang, XW[2]; Huang, JL[3]; Xu, YH[4]; Wu, XB[5].

Review question / Objective: **Population: Participants who were definitively diagnosed with chronic pruritus (pruritus duration >6 weeks) were included. No limitations of location, educational background, and gender were imposed. This study will only consider randomized controlled trials (RCTs) of Chinese herbal medicine for the treatment of patients with chronic pruritus . However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCT s, were excluded. Intervention: Chinese herbal medicine. Comparison: The control intervention based on the treatment guidelines of chronic pruritus, or placebo. Outcome: Primary outcomes: A visual analogue scale (VAS) score. Secondary outcomes: DLQI, Effective, Recurrence rate, Adverse Effects rate and other outcomes recorded in the article. Study design: This meta-analysis is secondary study and the data were extracted from other people's work.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 June 2022 and was last updated on 26 June 2022 (registration number INPLASY202260103).

INTRODUCTION

Review question / Objective: **Population: Participants who were definitively diagnosed with chronic pruritus (pruritus duration >6 weeks) were included. No limitations of location, educational background, and gender were imposed. This study will only consider randomized controlled trials (RCTs) of Chinese herbal medicine for the treatment of patients with chronic pruritus . However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCT s, were excluded. Intervention: Chinese herbal medicine. Comparison: The control intervention based on the treatment guidelines of chronic pruritus, or placebo.**

Outcome: Primary outcomes: A visual analogue scale (VAS) score. Secondary outcomes: DLQI, Effective, Recurrence rate, Adverse Effects rate and other outcomes recorded in the article. Study design: This meta-analysis is secondary study and the data were extracted from other people's work.

Condition being studied: Chronic pruritus (CP), defined as an unpleasant sensation lasting more than six weeks that induces the urge to scratch , is a disorder often associated with skin diseases (eg, psoriasis, atopic dermatitis [AD] , lichen planus [LP], etc.) and systemic diseases such as including end-stage renal disease (ESRD), diabetes, hypothyroidism, chronic hepatobiliary disease or malignancy are common and distressing symptoms . Population-based studies suggest that in the general population, chronic pruritus is experienced at least once in a lifetime by five individuals, with a 12-month incidence of 7 percent . In patient populations, its incidence is much higher, depending on the underlying etiology, ranging from 25% in hemodialysis patients to skin conditions such as urticaria and atopic dermatitis (AD) 100% of patients. CP can lead to sleep disturbance, fatigue, inability to work, anxiety, depression, etc., resulting in a significant decline in various areas of health-related quality of life (HRQoL). Furthermore, CP imposes a significant burden on society in terms of healthcare costs and treatment challenges.

METHODS

Search strategy:
#10 #3 AND #6 AND #9
#9 #7 OR #8
#8 'controlled trial':ab,ti OR randomized*:ab,ti OR 'randomised controlled study':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized clinical trial':ab,ti OR 'randomized controlled study':ab,ti OR trial:ab,ti OR 'randomized controlled':ab,ti
#7 'randomized controlled trial'/exp
#6 #4 OR #5
#5 itch:ab,ti OR itching:ab,ti OR pruritis:ab,ti OR 'chronic pruritus':ab,ti OR 'chronic itch':ab,ti
#4 'pruritus'/exp
#3 #1 OR #2
#2 'chinese herbal medicine':ab,ti OR 'chinese traditional medicine':ab,ti OR 'medicine, chinese traditional':ab,ti OR 'traditional chinese medicine':ab,ti
#1 'chinese medicine'/exp.

Participant or population: Participants who were definitively diagnosed with chronic pruritus (pruritus duration >6 weeks) were included. No limitations of location, educational background, and gender were imposed.

Intervention: Chinese herbal medicine.

Comparator: The control intervention based on the treatment guidelines of chronic pruritus, or placebo.

Study designs to be included: This study will only consider randomized controlled trials (RCTs) of Chinese herbal medicine for the treatment of patients with chronic pruritus . However, other studies, such as animal studies, reviews, case studies, non-controlled studies, and quasi-RCT s, were excluded.

Eligibility criteria: Chinese medicine for the treatment of chronic pruritus. Studies that met the following criteria were included: (1) the trial design was a randomized controlled trial, with or without blinding, and published in any language; (2) the subjects were eligible for chronic pruritus (pruritus duration >6 weeks) [2], Chronic pruritus refers to systemic itching of the skin; (3) Participants of all ages have no restrictions on gender, age, race, duration and other concomitant diseases; (4) The experimental group includes traditional Chinese medicine, external therapy or Combination therapy with traditional Chinese medicine and other therapies, regardless of the dosage form used (eg, proprietary Chinese medicine, Chinese herbal decoction, granules, capsules, tablets, pills, or injections). The control group was treated with comfort therapy

(such as placebo or blank control) or other therapy (such as western medicine, conventional treatment of disease or other non-drug therapy). (5) The pruritus index (using a visual analog scale (VAS) [12]) must be reported in the study.

Information sources: PubMed 、Embase, web of science、Cochrane, Clinical Trials.gov, Chinese Biological Medicine (CBM), China National Knowledge Infrastructure (CNKI), VIP, and Wan fang database.

Main outcome(s): A visual analogue scale (VAS) score.

Additional outcome(s): DLQI, Effective, Recurrence rate, Adverse Effects rate and other outcomes recorded in the article.

Quality assessment / Risk of bias analysis: Two investigators will separately assess the risk of bias of the selected RCTs using the Cochrane risk of bias assessment tool. The evaluation of each study mainly included the following seven aspects: random sequence generation, allocation hiding, blinding of participants and personnel , blinding of outcome assessment, incomplete outcome data, incomplete outcome data, selective outcome reporting, and other biases. Finally, the bias of the study will be rated on three levels: “low”, “high”, and “ambiguous”. These even domains will be separately appraised by two reviews, and discrepancies will be addressed by consulting a third reviewer.

Subgroup analysis: We will investigate the source of heterogeneity using subgroup analysis based on different interventions, controls, and outcomes.

Sensitivity analysis: We will carry out a sensitivity analysis to investigate the robustness and stability of outcome results by removing low methodological quality studies. The main analysis points included the impact of method quality, sample size, and missing data on the study. In this way, we will be able to assess the impact of individual studies on the overall results and determine whether the results are strong.

Country(ies) involved: China.

Keywords: traditional Chinese medicine, chronic pruritus, pruritus degree, systematic review, meta-analysis.

Contributions of each author:
Author 1 - Wang Jie.
Author 2 - Yang Xinwei.
Author 3 - Huang Jianli.
Author 4 - Xu Yihua.
Author 5 - Wu Xianbo.