

INPLASY PROTOCOL

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
The authors declare no conflicts of interest.

Plum-blossom needle plus Chinese herbal medicine for alopecia areata: A systematic review and meta-analysis protocol

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Review question / Objective: To assess the beneficial effect and safety of Plum-blossom needle plus Chinese herbal medicine for alopecia areata.

Condition being studied: Alopecia areata (AA) is an autoimmune disorder characterized by patches of non-scarring alopecia affecting scalp and body hair that can be psychologically devastating. AA is clinically heterogenous, and its natural history is unpredictable. Plum-blossom needle plus Chinese herbal medicine reported to be efficacious and widely used for the treatment of AA . This protocol aims to systematically review the results of randomized controlled trials (RCTs) with Plum-blossom needle plus Chinese herbal medicine, and to evaluate the benefits and safety of alopecia areata.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 August 2020 and was last updated on 09 August 2020 (registration number INPLASY202080038).

INTRODUCTION

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METHODS

Participant or population: Patients with alopecia areata.

Intervention: The treatment group was mainly Plum-blossom needle plus Chinese herbal medicine therapy.

Comparator: The comparison group consisted of those receiving routine care or any intervention other than Plum-blossom needle plus Chinese herbal medicine therapy.

Study designs to be included: A randomized controlled trial (RCT) study on Plum-blossom needle plus Chinese herbal medicine therapy treatment of alopecia areata , published in any.

Eligibility criteria: Types of study: All randomized controlled trials (RCT s) study on Plum-blossom needle plus Chinese herbal medicine therapy treatment of alopecia areata. Others such as case reports, animal experiments, non-RCTs, or RCT protocol will be excluded.

Information sources: Pubmed, Embase, Cochrane Library, Chinese Biomedical Literatures Database (CBM), China National Knowledge Infrastructure (CNKI) , Wan Fang Database (WF), Chinese Scientific Journal Database (VIP).

Main outcome(s): The effective rate, security.

Data management: (1) We will use NoteExpress 3.2.0.7535 and Excel software 11.1.0.9912 to extract data. The content will be saved in electronic form. (2) Different review authors will independently screen the titles and abstracts of records obtained

by searching the electronic databases to determine potential eligibility. Full texts screening and data extraction will be conducted afterwards independently. Any disagreement regarding study selection will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use NoteExpress 3.2.0.7535 .(3) The research team designed structured data extraction tables, including: the first author, nationality, publication year, patients' basic information, sample size, intervention measures of test group, intervention measures of controlled group, target outcome (including primary outcome measures and secondary outcome measures), etc.

Quality assessment / Risk of bias analysis: Risk of bias analysis: Included randomised studies will be assessed for risk of bias by two independent raters (TGH/CJ) using the Cochrane Collaboration Bias Risk Assessment Tool for the extracted methodological features in randomised trials. Any disagreements will be resolved through discussion or consultation with a third reviewer (XJ). According to the improved Jadad scoring scale, the quality of the included literature was evaluated. 1-3 were classified as low quality and 4-7 as high quality.

Strategy of data synthesis: Strategy of data synthesis: Meta analysis was performed using RevMan 5.4 provided by the Cochrane collaboration network. Relative risk (RR) was used for the two categorical variables, and mean difference (MD) was used for the Continuous variables. Both were expressed with 95% confidence intervals (CI). The heterogeneity test between the results of the included studies was performed using the I² test. The I² value reflects the proportion of the total variation in the effect size due to the existence of heterogeneity. (I² > 50%, indicating that heterogeneity is more obvious. If there is not obvious heterogeneity between the research results (I² ≤ 50%), the source of the heterogeneity is analyzed first, which may lead to heterogeneity factors for subgroup analysis. If statistical heterogeneity exists

in each subgroup without clinical heterogeneity, a random effects model is used for analysis. If the heterogeneity is too large and the results cannot be combined, a descriptive analysis is used and a sensitivity analysis is performed if necessary.

Subgroup analysis: Subgroup analysis will be handled according to the differences in Plum-blossom needle plus Chinese herbal medicine methods, patient conditions, and control.

Sensibility analysis: Sensitivity analyses will be performed to verify the robustness of the review conclusions. The impacts of study design, methodological quality, and missing data will be evaluated. Sensitivity analyses were planned by studies considered being at low risk of bias.

Country(ies) involved: China.

Keywords: Chinese herbal medicine; plum-blossom needle; alopecia areata ; systematic review; meta-analysis; protocol.

Contributions of each author:

Author 1 - Genhua Tang - the author drafted the manuscript.

Author 2 - Jun Xiong - revise this protocol.

Author 3 - Jun Chen - data collection ; analysis of results.