

INPLASY PROTOCOL

To cite: Zhang et al. The effectiveness and safety of acupuncture and moxibustion in the treatment of acute mastitis: a systematic review and meta-analysis program. Inplasy protocol 202160012. doi: 10.37766/inplasy2021.6.0012

Received: 05 June 2021

Published: 05 June 2021

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Support: 202130598.

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

Conflicts of interest:
None declared.

The effectiveness and safety of acupuncture and moxibustion in the treatment of acute mastitis: a systematic review and meta-analysis program

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Review question / Objective: Acute mastitis is usually related to breastfeeding and is a benign acute purulent disease of the breast. It can occur at any stage of lactation, and its main manifestations include non-cyclical breast tenderness, areola lumps, inverted nipples, poor milk discharge, and nipple fistulas. Modern medicine is mainly surgical and antibiotic treatment, but there are problems such as easy relapse and affect breast milk. Clinical practice shows that acupuncture treatment of mastitis can significantly improve the curative effect, prevent recurrence, and has certain therapeutic advantages, but there is a lack of evidence-based medicine.

Condition being studied: Acute mastitis. We will only include RCTs that are more likely than other study designs to provide impartial details. RCTs assessing the efficacy of acupuncture in the treatment of Acute mastitis will include, whether blinded or not. The following types of articles will be excluded: case reports, observational studies, retrospective studies, animal experiments, and review articles. No restrictions on language and publication time.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 June 2021 and was last updated on 05 June 2021 (registration number INPLASY202160012).

INTRODUCTION

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areola lumps, inverted nipples, poor milk discharge, and nipple fistulas. Modern medicine is mainly surgical and antibiotic treatment, but there are problems such as easy relapse and affect breast milk. Clinical practice shows that acupuncture treatment of mastitis can significantly improve the curative effect, prevent recurrence, and has

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METHODS

Participant or population: Among patients with definite diagnosis of Acute mastitis, nationality, race, age, sex, course of disease, and so on were unlimited.

Intervention: We will include acupuncture and acupuncture-related therapies (regular acupuncture, scalp acupuncture, auricular acupuncture, electroacupuncture, fire needling, intradermal needling, Moxibustion, and catgut embedding acupuncture) to comprehensively describe the effects of acupuncture on patients with acute mastitis. Clinical trials with other forms of stimulation including bleeding therapy, cupping, laser acupuncture, pharmacopuncture, acupotomy, point injection, or acupressure, will be excluded. Additionally, limitations to intervention intensity, frequency, and duration were not involved.

Comparator: Among patients with definite diagnosis of Acute mastitis, nationality, race, age, sex, course of disease, and so on were unlimited.

Study designs to be included: This study evaluated the effectiveness and safety of acupuncture combined with western medicine in the treatment of acute mastitis from the aspects of effective rate, symptom score, recurrence rate, adverse reaction rate and patient satisfaction.

Eligibility criteria: We will only include RCTs that are more likely than other study designs to provide impartial details. RCTs assessing the efficacy of acupuncture in the treatment of Acute mastitis will include, whether blinded or not. The following types of articles will be excluded: case reports, observational studies, retrospective studies, animal experiments, and review articles. No restrictions on language and publication time.

Information sources: From the establishment of the database to June 2021, computer search of English databases (PubMed, Embase, Web of Science, Cochrane Library) and Chinese databases (CNKI, Wanfang, VIP, China Biomedical Database) were used to conduct randomized controlled trials (RCT)) Acupuncture treatment of acute mastitis, two researchers independently extracted data and assessed the quality of the included studies, and used RevMan5.3 software to conduct a meta-analysis of the included literature.

Main outcome(s): Primary outcome: the overall effective rate; total effective rate = (cure number + effective number) / total number × 100% (Diagnostic and curative effect criteria of TCM diseases and syndromes of National Administration of TCM 2000: Evaluation Criteria for the efficacy of PCM,[14] Cure: no recurrence within 6 months after withdrawal of the drug, breast lump has been significantly reduced and pain has been significantly dissipated. Effective: breast lumps and pain have been locally dissipated more than half; Invalid: no improvement or further exacerbation of clinical symptoms.) 4. Secondary outcomes: Symptom score; Recurrence rate; Incidence of adverse reactions; Patient satisfaction.

Quality assessment / Risk of bias analysis: 2 reviewers (RH and MM) will extract the title, first author, publication year, country, language, journal source; information of participants: sex, age, study design, sample size, intervention, type of measures, risk of bias assessment, and findings from included studies with Excel

file. The results will be cross-checked by the 2 reviewers, and any disagreements will be resolved by consensus, with any ongoing differences in opinion being arbitrated by a third reviewer (HW). Grading of recommendations assessment, development, and evaluation reliability study (GRADE) will be implemented to assess the quality of evidence. Based on the risk of bias, inconsistency, imprecision, indirection, and publication

Strategy of data synthesis: We will use the Review Manager 5.4 software provided by the Cochrane Collaborative Network for statistical analysis. For continuous variables, the mean and SD of each study were obtained and pooled as mean difference (MD) or standardized mean differences (SMD) with a 95% confidence interval (CI). Statistical heterogeneity analysis was performed for the included clinical RCTs. The Cochrane I² test was used for statistical analysis. When I² was .05, it indicated that there was no statistical heterogeneity between the studies, and the fixed-effect model was selected to combine the effect amount; otherwise, the random effect model was adopted.

Subgroup analysis: The literature quality of this study was evaluated using the bias risk table proposed by the Cochrane Collaborative Network. The risk table includes 6 items: random sequence generation mode, whether to use allocation concealment, whether to blind the subjects and intervention providers, whether to blind the results evaluators, whether the results data are complete, whether to select the results report, and other bias sources. The criteria used to assess the risk of bias were “low risk,” “high risk,” and “unclear.” In this process, 2 evaluators independently evaluated methodological quality. In cases of disagreement, the third author intervened.

Sensitivity analysis: Before the combination of effect size, we will use Stata to assess the available study and patient characteristics to ensure similarity and to investigate the potential effect of heterogeneity on effect estimates. When

interstudy heterogeneity exists, a random effects model is used. For comparison of each pair, heterogeneity was assessed by the statistic I². When I² > 50%, this indicates that there is heterogeneity between studies, and the source of heterogeneity should be further investigated. When I² < 50%, interstudy heterogeneity was considered to be small, or there was no obvious heterogeneity.

Country(ies) involved: China.

Keywords: Acupuncture, mastitis, randomized controlled trial, systematic review.

Contributions of each author:

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Author 2 - Qinqin Xu.