INPLASY PROTOCOL

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The authors declare no conflicts of interest.

Effect of fire needle for ganglion cysts: a protocol of systematic review and meta-analysis of randomized controlled trials

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Review question / Objective: **To systematically evaluate the efficacy of fire needle versus conventional acupuncture and other non-fire needle therapy in the treatment of ganglion cysts.**
Condition being studied: **Ganglion Cysts are cystic masses occurring in the tendon sheath of joint, which are caused by degeneration of the connective tissue in the joint capsule, ligament and tendon sheath. Ganglion cyst can be seen in any age, young and middle-aged, the incidence of disease has a significant gender difference, female incidence can be 3 times as male. The most common site of the disease is the dorsal part of the wrist, followed by the palmar, palm, toe, dorsal foot, both sides of the knee joint and the Pal nest can also occur. In recent years, the incidence of ganglion cyst increases year by year, which brings inconvenience to people's life. With the application of clinical practice, fire needle therapy, as a traditional green therapy, not only has remarkable curative effect, but also is easy to operate with few side effects.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 August 2020 and was last updated on 08 August 2020 (registration number INPLASY202080032).

INTRODUCTION

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METHODS

Participant or population: Patients with ganglion cysts.

Intervention: Fire needle therapy, or fire needle combined with other acupuncture treatments.

Comparator: Conventional acupuncture, Western medicine, placebo, sham acupuncture, no treatment, or any combination of these.

Study designs to be included: Randomized controlled trials - Routine acupuncture, Western medicine, placebo, sham acupuncture, no treatment, or any combination of these.

Eligibility criteria: Subjects: patients with ganglion cyst, age and sex were not restricted. Intervention measures: fire needles or fire needles combined with other acupuncture and moxibustion were used as the intervention measures in the treatment group, while conventional acupuncture or other non-fire needle therapy was used as the intervention measures in the control group Outcome measures: cure rate, effective rate, inefficiency, recurrence rate, adverse reactions.

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

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

Additional outcome(s): Recurrence rate, adverse reactions.

Quality assessment / Risk of bias analysis: 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. Risk of bias analysis:Included randomised studies will be assessed for risk of bias by two independent raters(CJ/ZSY) using the Cochrane Collaboration's tool for assessing risk of bias in randomised trials. Any disagreements will be resolved through discussion or consultation with a third reviewer(XJ).

Strategy of data synthesis: RevMan 5.4 software (Cochrane Collaboration) was used for the meta-analysis. Dichotomous data were reported as risk ratio (RR) with 95% confidence intervals (CI), while continuous data were reported as standardized mean difference (SMD) with 95% CIs. The Higgins I^2 test was used to test heterogeneity with a significance level set at 50%. If heterogeneity was not significant ($I^2 \leq 50\%$), the fixed effects model was used for meta-analysis. Otherwise, the random effects model was used ($I^2 \geq 50\%$). If possible, we investigated the potential explanations for heterogeneity and conducted subgroup analysis.

Subgroup analysis: If the necessary data are available, subgroup analysis will be carried out according to different factors as follows: 1. Control interventions (eg, sham/placebo acupuncture, massage ,no treatment, or non-TCM treatment). 2.Type of acupuncture and moxibustion (eg, needle acupuncture, electronic-acupuncture, auricular acupuncture, heat-sensitive moxibustion, Thunder fire moxibustion , warm needling moxibustion , suspended moxibustion or mild

moxibustion). 3.Outcome indicators (eg, recurrence rate, adverse reactions).

Sensibility analysis: To assess the influence of each individual study, leave-one-out sensitivity analysis was performed iteratively by removing one study at a time to confirm that the findings were not influenced by any single study.

Country(ies) involved: China.

Keywords: Ganglion Cysts; Fire Needle; Acupuncture.

Contributions of each author:
Author 1 - Jun Chen - The author drafted and improved the manuscript.
Author 2 - Jun Xiong - Revise this protocol; search strategy.
Author 3 - Si-Yuan Zhu - The author contributed to the development of the selection criteria, and the risk of bias assessment strategy.