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.

Efficacy of fire needle on patients of facial spasm: A protocol of meta-analysis and systemic review

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Review question / Objective: Whether fire needle therapy is effective for patients with facial spasm.

Condition being studied: Facial spasm, also known as facial convulsion, is characterized as involuntary and irregular paroxysmal convulsion of the facial muscles, which mostly occurs in the middle-aged and the aged. It usually begins with eye, extending to mouth circumference gradually, and half of the face is affected finally. In general, there is one side affected, both sides of the face affected occasionally. Along with the disease progress, the convulsion gets more and more violent and the attacking time also gradually extended, which affecting the work and life of patients seriously. Currently, the treatment of the disease includes eating drugs and multi-point injection of botox, but there are adverse reactions and high recurrence rate. In addition, minimally invasive surgery is adopted, but the operation is complicated, and postoperative complications and long-term efficacy are uncertain. Previous evidence suggests that fire needle treatment may have beneficial effect in treating facial spasm.

INTRODUCTION

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METHODS

Participant or population: The patient was diagnosed with facial spasm.

Intervention: Fire needle.

Comparator: Non-acupuncture therapy, including western medicine, traditional Chinese medicine, surgery, conventional treatment, placebo, waiting treatment group or no treatment.

Study designs to be included: All randomized controlled primary studies on the treatment of facial spasm with fire needles.

Eligibility criteria: Published original research data in Chinese or English that meets randomized control criteria will be considered for inclusion in this review.

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): Clinical cure rate: the number of participants who made a full recovery; total effectiveness rate: the number of participants who showed a positive response to therapy. According to the the frequency and intensity of the disease.

Quality assessment / Risk of bias analysis: Included in a risk of bias table created by Statistical Software RevMan5.4, all studies will be assessed from five aspects recommended by Cochrane Handbook: selection bias; performance bias; detection bias; attrition bias; reporting bias. There are seven items in the risk of bias table: randomisation sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective outcome reporting; other bias. Each item assesses risk of bias according to three levels: unclera risk, low risk, and high risk. The assessment outcome can be displayed as a graph or summary.

Strategy of data synthesis: RevMan 5.4 software provided by the Cochrane Collaboration Network was used. Statistical analysis was carried out for the extracted data. Because of different conditions of researchers, subjects and locations included in the articles, the heterogeneity test was conducted first, and then the effect model was selected. The fixed effect model was used for the data with uniform numerical units. In the case of unexplainable heterogeneity, the random effect model can be combined. Subgroup analysis was performed for the data with high heterogeneity. Bivariate data were expressed as odds ratio (OR) and 95% confidence interval (CI). Continuous data were represented as mean difference (MD) and 95%CI.

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 moxibustion, no treatment, oth er TCM treatment or non-TCM treatment). 2. Type of acupuncture and moxibustion (eg, needle acupuncture, electro-acupuncture, auricular acupuncture, heat-sensitive moxibustion, thunder fire miraculous moxa roll , warm needling moxibustion , suspended moxibustion or mild moxibustion).

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: Facial spasm; Fire needle; System evaluation.

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