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.

Effectiveness and safety of fire needle for Knee Osteoarthritis : a protocol of systematic review and meta-analysis

Lu, L[1]; Xiong, J[2]; Chen, J[3].

Review question / Objective: To evaluate the effectiveness and safety of fire needle treatment for Knee Osteoarthritis patients.
Condition being studied: Knee osteoarthritis (KOA) is a chronic joint disease that is prone to middle-aged and elderly people.The main clinical manifestations were knee joint pain and joint activity disorder, among which pain was the chief complaint in clinic.
Information sources: Pubmed, Embase, Cochrane Library, Chinese Biomedical Literatures Database(CBM), China National Knowledge Infrastructure (CNKI) , WangFang Database (WF), Chinese Scientific Journal Database (VIP).

INTRODUCTION

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METHODS

Participant or population: Knee osteoarthritis patients, regardless of age, gender.

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 (RCTs) which assessed the efficacy and safety of fire needle for Knee osteoarthritis will be included.

Eligibility criteria: Subjects: patients with Knee osteoarthritis, 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.

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): Outcome measures: cure rate, effective rate.

Data management: (1)We will use NoteExpress and Excel software 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)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, qualitative evaluation method, target outcome (including primary outcome measures and secondary outcome measures), etc. Different review authors will independently extract data. Any disagreement regarding data extraction will be resolved through discussion or arbitrated by the third author if necessary. In this step, we will use Excel.

Quality assessment / Risk of bias analysis: Included randomised studies will be assessed for risk of bias by two independent raters(Lunbin Lu and Jun Chen) 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(Jun Xiong).1 of 200 max words.

Strategy of data synthesis: Data synthesis will be conducted with RevMan V.5.4 software provided by the Cochrane Collaboration. Before data meta-analysis, we measure the heterogeneity with a standard test. Depending on the level of heterogeneity, those studies with high heterogeneity ($p>0.10$) will use fixed-effect model. We will use the RR for dichotomous data and SMD for continuous data and mean difference with 95% CIs. Those studies with low heterogeneity ($p=0.10$), we use the random-effect model. Subgroup or sensitivity analysis will be performed if necessary. We will use qualitative analysis if there is excessive data heterogeneity.

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.

Language: No restriction.

Country(ies) involved: China.

Keywords: Knee osteoarthritis；Fire Needle；Acupuncture.

Contributions of each author:
Author 1 - Lubin Lu - The author drafted and improved the manuscript.
Author 2 - Jun Xiong - Revise this protocol; search strategy.
Author 3 - Jun Chen - Data collection; analysis of results.