INPLASY PROTOCOL

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Conflicts of interest:
None.

Efficacy and safety of floating needle therapy in the treatment of knee osteoarthritis: a protocol for systematic review and meta-analysis

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Review question / Objective: **How about the efficacy and safety of floating needle therapy in the treatment of knee osteoarthritis.**
Condition being studied: **Knee osteoarthritis is a common clinical degenerative disease of the joints, which is prone to occur in middle-aged and elderly people. Its early manifestations include knee redness, swelling, pain, effusion and sound, etc. With the development of the disease, knee osteoarthritis will also lead to joint deformity and disability, which will seriously affect the living ability of patients. It not only brings physical pain and dysfunction to patients, but also leads to anxiety, helplessness, depression and social disorder in social psychology, which seriously affects patients' daily life, social function and life quality, and also brings huge economic burden and pressure to family and social medical treatment. Floating needle therapy has shown strong advantages in the treatment of KOA, and the curative effect is accurate. Therefore, this paper will carry out a systematic evaluation and meta analysis of the efficacy and safety of floating needle therapy in the treatment of KOA.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 December 2020 and was last updated on 30 December 2020 (registration number INPLASY2020120145).

INTRODUCTION

Review question / Objective: **How about the efficacy and safety of floating needle therapy in the treatment of knee osteoarthritis.**

Rationale: **A systematic review and meta-analysis of clinical randomized controlled studies on floating needle therapy for knee osteoarthritis following the rules of evidence-based medicine.**

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METHODS

Search strategy: We will search Eight electronic databases, including PubMed, Embase, Web of Science, Cochrane Library, the China National Knowledge Infrastructure(CNKI), Chinese Science and Technology Periodical Database(VIP), Wanfang Database(WF), and Chinese Biomedical Literature Database(CBM). We will search above electronic databases from the beginning to January 2021, without any language restriction.

Participant or population: There are clear and recognized diagnostic criteria and efficacy criteria, and all patients are diagnosed as knee osteoarthritis, regardless of gender, age and origin of the case.

Intervention: floating needle therapy, or mixed therapies based on floating needle therapy will also be include.

Comparator: The control group will receive one of the following treatment methods: conventional pharma-cological therapy, no treatment, and placebo.

Study designs to be included: Clinical randomized controlled trials (RCTs) containing floating needle therapy for knee osteoarthritis were included, with no limitation of language and publication status.

Eligibility criteria: Reported in chinese and English, and meet the "PICOS", will be considered for inclusion in this overview.

Information sources: Eight electronic databases will be searched, including PubMed, Embase, Web of Science, Cochrane Library, the China National Knowledge Infrastructure(CNKI), Chinese Science and Technology Periodical Database(VIP), Wanfang Database(WF), and Chinese Biomedical Literature Database(CBM). We will search above electronic databases from the beginning to January 2021, without any language restriction.

Main outcome(s): Clinical efficacy, including total effective rate or cure rate, VAS pain score, and recurrence rate will be accepted as the primary outcomes.

Additional outcome(s): The changes of TCM symptom score, inflammatory factor level change, knee function score will be used as secondary outcomes.

Data management: The two researchers independently read the title and abstract of the literature we obtained, read the full text of the trials that might meet the inclusion criteria to determine whether the inclusion criteria were truly met, and discussed the conflicting literatures or let the third researcher decide whether to include them. Two researchers independently extracted data from the included studies, including study design, intervention measures and methods, measurement indicators, results, methodological contents such as hidden grouping and blind method, etc., and a third evaluator checked the consistency of the data. If the required information is incomplete, we will contact the original author for the required data.

Quality assessment / Risk of bias analysis: Two evaluators independently select the literature according to the inclusion and exclusion criteria and cross-check. In case

of disagreement, a third evaluator will assist in the decision. The extracted data included the first author, year of publication, number of patients, age, gender, intervention measures, outcome indicators, etc. The Jadad scale to evaluate quality into literature, including: random sequence (right 2 points, 1 points not clear, inappropriate 0), distribution, hidden (right 2 points, 1 points not clear, inappropriate 0), blinded (right 2 points, 1 points not clear, inappropriate 0), lost to follow-up and exit (describe 1 points, not describe 0); 0-3 is classified as low quality and 4-7 as high quality.

Strategy of data synthesis: Meta analysis will be performed using Rev Man5.3.0 software. The odds ratio (OR) and its 95% Confidence Interval (CI) will be used as the counting data, while the weighted mean difference (WMD) and its 95% CI will be used as the measurement data.

Subgroup analysis: If heterogeneity exists in the meta-analysis, the source of heterogeneity should be sought, such as whether the degree of disease, treatment cycle, treatment time of each floating needle, type of intervention, etc., is the source of heterogeneity. If so, a subgroup analysis should be conducted for these reasons to see whether heterogeneity still exists after analysis.

Sensibility analysis: Sensitivity analysis can not only assess the stability and reliability of the combined results, but also assess whether the combined results are significantly changed by the influence of a single study. If sufficient literature is included, we will adopt the method of excluding literature one by one, excluding each included study one by one before effect-size combination, changing the inclusion and exclusion criteria or excluding certain types of literature before effect-size combination.

Language: No limitation of language.

Country(ies) involved: China.

Keywords: Floating needle therapy; Knee osteoarthritis; protocol; Systematic review and meta-analysis.

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