INPLASY PROTOCOL

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Review Stage at time of this submission: Preliminary searches.

Conflicts of interest: None.

INTRODUCTION

Review question / Objective: What is the efficacy of acupoint catgut embedding on sciatica?

Condition being studied: Sciatica.

Acupoint Catgut Embedding for the Treatment of Sciatica: A protocol for a systematic review

Zhang, Y1; Zhang, Y2; Chen, X3; Tan, S4; Zhou, Z5.

Review question / Objective: What is the efficacy of acupoint catgut embedding on sciatica?

Condition being studied: Sciatica.

Information sources: The main information source will include electronic resource databases, clinical registries. The search strategy will be conducted following the Cochrane Handbook guideline. The Cochrane Library, PubMed, Springer Medline, EMBASE, Web of Science, CNKI, WANFANG, CBM and VIP databases are the main electronic resource databases used to search the key words. Clinical registries include the Chinese Clinical Trial Registry Centre (http://www.chictr.org.cn/) and the WHO International Clinical Trials Registry Platform (ICTRP) (https://clinicaltrials.gov/) searched for ongoing trials.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 November 2020 and was last updated on 20 November 2020 (registration number INPLASY2020110087).

METHODS

Participant or population: Participants who are diagnosed with sciatica will be included and the diagnostic criteria must meet the

acknowledged standards at home and abroad. There is no limit between gender and race. Patients will be excluded with low back pain caused by spinal tumors, cauda equina syndrome, and the patients with pregnancy will be absolutely excluded.

Intervention: 1acupoint catgut embedding as the only therapy for sciatica in clinical will be included. 2Invention comparing different acupoints scheme of ACE will be excluded. 3The treatment group will not restrict the ACE materials, the course and frequency of treatment.

Comparator: Control inventions including different types of acupuncture without ACE, traditional Chinese medicine, western medicine, placebo, or sham ACE will be considered.

Study designs to be included: Only the randomized controlled trials (RCTs) compared ACE therapy with other interventions conducted in human will be included, language and blinding will not be limited. Non-randomized clinical trials, observational study, case reports, animal mechanism studies will not be considered.

Eligibility criteria: All the RCTs or quasiRCTs of acupoint catgut embedding for patients with sciatica will be included without publication status restriction, review articles, case reports, conference abstracts, cross-sectional studies, and all observational studies will be excluded.

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Main outcome(s): The main outcomes are the pain intensity and the whole efficiency assessment. Pain visual analogue scale (VAS) score, six-point behavior (BRS-6) score, modified Japanese Orthopaedic Association (JOA) score will be used to measure the pain intensity. The proportion of patient improvement will be used to assess the whole efficiency.

Additional outcome(s): Oswestry Disability Index (ODI), life quality(EQ-5D scale, Medical Outcomes Study 36-item Short Form health survey (SF-36 scale)), physical examination and adverse events all will be taken into consideration.

Quality assessment / Risk of bias analysis:

The assessment of the risk of bias in the included studies will use the Cochrane Collaboration Risk of Bias Tool[25], which will be conducted by 2 reviewers(ZYJ and ZYR) and another reviewer (XC) will assist in resolving the disagreements. There are 7 aspects used to evaluate the risk of bias: random sequence generation, allocation concealment, the blinding method for participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias.

Strategy of data synthesis: RevMan (V.5.3) will be used to calculate the RR with 95% CI for dichotomous data and the MD for continuous variables. If I2≤50%, a fixed effect model will be used for the metaanalysis. If I2>50%, a meta-analysis will be performed using a random effects model after further analysis of the heterogeneity of the sources. Text will be provided to summarise the findings of the included publications when the data are not suitable to quantitatively combine. If trials reporting only has pre- and post-intervention values, the mean changes will be obtained according to subtracting the premeasurements from the postmeasurements. Respectively, the standard deviation (s.d.) for changes will be estimated.

Subgroup analysis: The type of control group and the frequency of treatment will be the basis of the subgroup.

Sensibility analysis: Only the test for heterogeneity of p value is less than 0.1 after subgroup analysis, the sensitivity analysis will be conducted. The low quality studies will be excluded, and the meta-analysis will be performed again.

Language: English.

Country(ies) involved: China.

Keywords: Acupoint Catgut Embedding; satica; acupuncture; Systematic Review; Study Protocol.

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