INPLASY PROTOCOL

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest: None.

Effectiveness and safety of warm needle acupuncture on lumbar muscles strain: Protocol for a systematic review and meta-analysis

Huang, YS[1]; Cheng, C[2]; Xie, L[3]; Zhu, XH[4]; Chen, DM[5]; Cheng, CS[6].

Review question / Objective: Can warm needle acupuncture treat lumbar muscle strain safely and effectively?

Condition being studied: Lumbar muscle strain (LMS) ;Warm needle acupuncture (WNA).

Information sources: The following electronic databases will be searched from inception to NOV. 2020: 5 English databases [PubMed,Cochrane Library, EMBASE, Web of Science, WHO International Clinical Trials Registry Platform (TCTRP)],and 4 Chinese databases [Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure Database (CNKI), Chinese Scientific Journals Database (VIP) and the Wanfang Database] . We will also search the authors personalfiles to make sure that all relevant material has been captured. Various combinations of Medical Subject Headings and non-MeSH terms will be used, including LSM,WNA, and RTCs. For example ,the search strategy on PubMed are as follows: warm needle acupuncture(eg,"warm needle acupuncture" or "silver-needle warm acupuncture"or "needle warming moxibustion" or "moxibustion with warming needle" or "needle warming moxibustion" or "needle Warming Therapy" or "warming acupuncture" or "Wen Zhen"); lumbar muscle strain(eg, "lumbar muscle strain" or "the strain of psoas muscle" or "psoas muscle" or "Strain of lumbar muscles" or "lumbar muscle degeneration" or "psoatic strain").

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 December 2020 and was last updated on 20 December 2020 (registration number INPLASY2020120100).

INTRODUCTION

Review question / Objective: Can warm needle acupuncture treat lumbar muscle strain safely and effectively?

Condition being studied: Lumbar muscle strain (LMS) ;Warm needle acupuncture (WNA).

METHODS

Search strategy: We will search the following database sources for the Randomized controlled trials: PubMed, Cochrane Library, EMBASE, Web of Science, WHO International Clinical Trials Registry Platform (TCTRP) ,Chinese Biomedical Literature Database (CBM), Chinese National Knowledge Infrastructure Database (CNKI), Chinese Scientific Journals Database (VIP) and the Wanfang Database. All randomized controlled trials of WNA for Lumbar muscle strain (LMS)in the above database will be considered for inclusion, and high-quality articles will be screened for data extraction and analysis, to summarize the therapeutic effect of WNA on LMS patients.

Participant or population: We will include studies on patients that have been diagnosed as LMS by clinicians based on Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis & Treatment of Low Back Pain ,VA/DoD Clinical Practice Guideline: Diagnosis and Treatment of Low Back Pain, and Criteria for Diagnosis and Efficacy of TCM Diseases. There will be no restriction on age, gender, ethnicity, and profession.

Intervention: Studies applied WNA in the experimental group will be included.

Comparator: The therapeutic intervention of controlled group can be other therapies such as conventional acupuncture, electro-acupuncture, auriculo-acupuncture or pharmacological therapy.

Study designs to be included: All available randomized controlled trials (RCTs) on WNA for lumbar muscle strain will be included. Others such as retrospective study, case report, review, and studies which uses inappropriate random sequence generation methods will be excluded.

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Main outcome(s): The primary outcome is the variety of Oswestry Disability Index (ODI) and the visual analog scale (VAS).

Additional outcome(s): Inflammatory factors :The change of inflammatory factors such as TNF-α、IL-6、CRP, etc. Activity of Daily Living Scales (ADL). JOA back pain evaluation questionnaire (JOABPEQ). Adverse events caused by WNA, such as dizziness, nausea, vomiting, weariness, etc.

Quality assessment / Risk of bias analysis: Two authors independently assessed the methodological quality of each trial according to the standards advised by the

Cochrane Handbook For Systematic Reviews of Interventions. Any disagreements were resolved by discussion and reached consensus through a third reviewer . We will assess the following domains: random sequence generation, allocation concealment, blinding to participants, personnel and outcome, incomplete outcome data, selective reporting, and other biases to evaluate the risk of bias of all included studies. Through our discussion, we will resolve any discrepancies in the assessment of risk of bias and consult an arbiter if it is necessary. Finally, we will divide the quality of the studies into 3 levels: "low risk of bias", "high risk of bias", and "unclear risk of bias".

Strategy of data synthesis: RevMan Software (V5.3, The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark)will conduct all data analysis. We will select a random effects model or fixed effects model to merge the primary and secondary outcome indicators in accordance with the results of heterogeneity test. if the heterogeneity is low (I2 <50%), we will apply the fixed effects model for data synthesis, while the random effects model will be conducted of the significant heterogeneity (I2≥50%). It is considered that differences are statistically significant if the results of Z test show that P value is less than 0.05, and the 95% CI does not contain 0 (for continuous variables) or the 95% CI does not contain 1 (for dichotomous variables).

Subgroup analysis: Once individual studies may consist of multiple treatment group, subgroup analysis will be performed to explain heterogeneity if possible. Factors such as following will be considered: # Patients characteristics (age, sex, personal constitution ,underlying diseases). # Duration and frequency of therapy.

Sensibility analysis: A sensitivity analysis will be carry to identify the quality and robustness of the meta analysis result once the outcome analyses involve a large degree of heterogeneity, according to

sample size, methodological quality, and the effect of missing data.

Language: Language will be restricted to Chinese and English.

Country(ies) involved: China.

Keywords: Acupuncture therapy;Warm needle acupuncture; Lumbar muscle strain; systematic review lumbar muscle strain.

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