

INPLASY PROTOCOL

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Support: None.

Review Stage at time of this submission: Piloting of the study selection process.

Conflicts of interest:
None.

INTRODUCTION

Review question / Objective: P: Patients diagnosed with cervical spondylotic radiculopathy. I: The treatment group will be treated with warming acupuncture (with/without additional treatment). No

Efficacy and safety of warming acupuncture in the treatment of cervical spondylotic radiculopathy: a protocol of a systematic review and meta-analysis

Li, Y¹; Wang, Z².

Review question / Objective: P: Patients diagnosed with cervical spondylotic radiculopathy. I: The treatment group will be treated with warming acupuncture (with/without additional treatment). No restrictions are imposed on times of treatment, frequency of treatment, and length of the treatment period. C: The treatment with several types of acupuncture (with/without same additional treatment) will be included in this review as acupuncture, acupoint sticking, cervical pull, acupoint injection, electroacupuncture and so on. S: Only randomized controlled trials (RCTs) will be included.

Condition being studied: Cervical spondylosis is a common and frequent clinical disease, among which nerve root type accounts for 70.2% of the patients with cervical spondylosis. People suffering from cervical spine disease will have a low sense of security, easy to produce anxiety mentality, affecting the health of the body.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 November 2020 and was last updated on 06 November 2020 (registration number INPLASY2020110025).

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METHODS

Search strategy: The following electronic bibliographic databases were searched from their inception until 30 September 2020: PubMed, Embase and the Cochrane Library, China National Knowledge Infrastructure (CNKI), the Chinese VIP database and Wangfang database. MeSH and free text terms were employed for searching. The literature search was performed in English and Chinese. The following search terms were used individually or combined: cervical spondylotic radiculopathy; nerve root cervical spondylotic; cervical spondylosis; cervical spondylopathy; cervical syndrome; neck pain; mechanical neck disorders; warming needle; moxibustion. Chinese search terms included: shenjinggen-xingjingzhuibing; wenzhenjiu; wenzhen and aijiu.

Participant or population: Patients diagnosed with cervical spondylotic radiculopathy.

Intervention: The treatment group will be treated with warming acupuncture (with/without additional treatment). No restrictions are imposed on times of treatment, frequency of treatment, and length of the treatment period.

Comparator: The treatment with several types of acupuncture (with/without same additional treatment) will be included in this review as acupuncture, acupoint sticking, cervical pull, acupoint injection, electroacupuncture and so on.

Study designs to be included: Randomized controlled trials (RCTs) will be included.

Eligibility criteria: Articles will be included if they are independent original RCTs.

Information sources: PubMed, Embase and the Cochrane Library, China National Knowledge Infrastructure (CNKI), the Chinese VIP database and Wangfang database.

Main outcome(s): Visual analog scale (VAS).

Additional outcome(s): Present pain index (PPI); total effective rate and Pain rating index (PRI).

Data management: Two authors will independently extract data. Any disagreement will be resolved by discussion until consensus is reached or by consulting a third author. The literature data extraction will be completed independently by 2 researchers and the data form uniformly developed by the researcher was filled out. The data extraction content includes the following: 1.General information: article title, first author, corresponding author, time of publication research, evaluation correspondence, contact information. 2.Research method: design pattern, ample size, random allocation, random hiding, blind method, baseline level. 3.Participants: Patients age, gender, cervical spondylotic radiculopathy diagnostic criteria, severity, ethnicity study, location. 4. Intervention: acupuncture and moxibustion point, period of treatment, treatment frequency. 5.Efficacy evaluation: main observation indicators; secondary observation indicators; safety indicators and number of adverse reactions.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: Random sequence generation

(selection Bias) Allocation concealment (selection bias) Blinding of participants and personnel (performance bias) Incomplete outcome data (attrition bias) Selective reporting (reporting bias) Other biases Results from these questions will be graphed and assessed using Review Manager 5.3.

of bias assessment, GRADE assessment, and data synthesis. Is the guarantor of the review.

Author 2 - Li Yan - Selection of studies and data extraction, writing of the project. search strategy, analysis of results. Selection of studies and data extraction, writing of the project.

Strategy of data synthesis: Risk ratio (RR) for both fixed and random effects models (weighting by inverse of variance) will be used. A continuity correction will also be used for cells with zero values. Between study heterogeneity will be assessed using the I^2 statistics. Results will be assessed using forest plots and presented as RRs for the main outcome and secondary outcomes. An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies. Publication bias will be assessed by a funnel plot for meta-analysis and quantified by the Egger method. Statistical analysis will be conducted using Review Manager software for Mac.

Subgroup analysis: If there is significant heterogeneity in the included trials, then we will conduct a subgroup analysis based on the warming acupuncture interventions with/without additional treatment and different outcomes.

Sensibility analysis: Whenever necessary, we will examine the stability of study results by eliminating low quality studies.

Language: Only Chinese and English.

Country(ies) involved: China.

Other relevant information: None.

Keywords: Warming acupuncture; cervical spondylotic radiculopathy; efficacy; safety.

Contributions of each author:

Author 1 - Wang Zuqing - Conceived the idea for this systematic review. Developed the methodology for the systematic review protocol. Developed the search strategy and will screen potential studies, perform duplicate independent data extraction, risk