

# INPLASY PROTOCOL

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The authors declare that they  
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## Electroacupuncture in the patients with spinal cord injury: a meta-analysis of randomized controlled trials

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**Review question / Objective:** Participants: Participant with SCI whether age, gender and ethnic. Intervention(s): Electroacupuncture treatment. Comparator(s): A blank control, a placebo control, a fake acupuncture control, and a western medicine control. Main outcome(s): Change in motor score and sensory score from baseline to the last available follow-up, measured using the ASIA score. Additional outcome(s): Change in ADL from baseline to the last available follow-up, measured using the Barthel. Change in residual urine volume from baseline to the last available follow-up, measured using the urinary dynamics test. Change in AIS grade from baseline to the last available follow-up, measured using the AIS grading.  
**Condition being studied:** Electroacupuncture, spinal cord injury and functional recovery.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 09 May 2020 and was last updated on 09 May 2020 (registration number INPLASY202050033).

### INTRODUCTION

**Review question / Objective:** Participants: Participant with SCI whether age, gender and ethnic. Intervention(s): Electroacupuncture treatment.

Comparator(s): A blank control, a placebo control, a fake acupuncture control, and a western medicine control. Main outcome(s): Change in motor score and sensory score from baseline to the last available follow-up, measured using the

**ASIA score. Additional outcome(s):** Change in ADL from baseline to the last available follow-up, measured using the Barthel. Change in residual urine volume from baseline to the last available follow-up, measured using the urinary dynamics test . Change in AIS grade from baseline to the last available follow-up, measured using the AIS grading.

**Rationale:** Spinal cord injury is a kind of central nervous system disease with a high disability rate caused by trauma. Reports have shown that electroacupuncture (EA) can effectively improve the quality of life of patients and reduce the occurrence of adverse reactions. Although a large number of clinical and experimental studies have confirmed the effectiveness of electroacupuncture in spinal cord injury, the evidence-based medicine is still lacking.

**Condition being studied:** Electroacupuncture, spinal cord injury and functional recovery.

## METHODS

**Search strategy:** All the literature (public publication, internal information, ongoing publication) on acupuncture treatment of SCI with no restriction on language and publishing status unpublished publication and so on will be included. We will make the Search strategy according to Cochrane Handbook for Systematic Review of interntions (Version 5. 1.0) which was constituted of SCI, Acupuncture and Random. Electronic searches: We will search the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE(1980-2020), Pubmed (1980-2020), Chinese Medical Database (CNKI, 1979.1.1-2020.05.01), Vip Citation Databases(Chongqing Veipu, 1989-2020), Wanfang(1990-2020). Searching other resources: We will search the reference lists of the identified trials to identify further relevant trials. We will also search on-line trial registries such as ClinicalTrials.gov (ClinicalTrials.gov/), European Medicines Agency (EMA)

([www.ema.europa.eu/ema/](http://www.ema.europa.eu/ema/)), WHO International Clinical Trials Registry Platform ([www.who.int/ictrp](http://www.who.int/ictrp)), the Food and Drug Administration (FDA) ([www.fda.gov](http://www.fda.gov)), as well as pharmaceutical company sources for ongoing or unpublished trials. 17. URL to search strategy. EMBASE search strategy as an example: ('electroacupuncture'/exp/mj OR 'electroacupuncture' ) AND('spinal cord injury' OR 'spinal cord injury'/exp/mj OR 'spinal cord trauma' OR 'spinal cord trauma'/exp/mj OR 'traumatic myelopathy ' OR 'traumatic myelopathy'/exp/mj OR 'spinal cord transection' OR 'spinal cord transection'/exp/mj OR 'spinal cord laceration' OR 'spinal cord laceration '/exp/mj OR 'post-traumatic myelopathy' OR 'post-traumatic myelopathy'/exp/mj OR 'post traumatic myelopathy' OR 'post traumatic myelopathy'/exp/mj OR 'Spinal Cord Contusion' OR 'Spinal Cord Contusion'/exp/mj) AND 'randomized controlled trial'/exp/mj AND [1980-2020]/py.

**Participant or population:** Participant with SCI whether age, gender and ethnic.

**Intervention:** Electroacupuncture treatment.

**Comparator:** A blank control, a placebo control, a fake acupuncture control, and a western medicine control.

**Study designs to be included:** Any randomised trials providing the highest level of evidence to assess the effects of interventions.

**Eligibility criteria:** This study will only include randomized controlled trials(RCTs) of electroacupuncture in the patients with spinal cord injury.

**Information sources:** All literatures on acupuncture treatment of SCI was included, with no restriction on language or publishing status (i.e. unpublished articles were included). Following the Cochrane Handbook for Systematic Review of Interventions (Version 5.1.0), the search terms used were 'spinal cord injury', 'acupuncture' and 'random'. Electronic

searches: We will search the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE(1980-2020), Pubmed(1980-2020), Chinese Medical Database (CNKI,1979.1.1-2020.03.31), Vip Citation Databases (Chongqing Veipu,1989-2020), Wanfang(1990-2020). Searching other resources: We will search the reference lists of the identified trials to identify further relevant trials. We also searched on-line trial registries such as ClinicalTrials.gov (ClinicalTrials.gov/), European Medicines Agency (EMA) ([www.ema.europa.eu/ema/](http://www.ema.europa.eu/ema/)), WHO International Clinical Trials Registry Platform ([www.who.int/ictrp/](http://www.who.int/ictrp/)), as well as ongoing or unpublished trials.

**Main outcome(s):** Change in motor score and sensory score from baseline to the last available follow-up, measured using the ASIA score.

**Additional outcome(s):** Change in ADL from baseline to the last available follow-up, measured using the Barthel. Change in residual urine volume from baseline to the last available follow-up, measured using the urinary dynamics test. Change in AIS grade from baseline to the last available follow-up, measured using the AIS grading.

**Data management:** Both authors will independently extract the following data from each trial using EpiData 3.1. 1. The basic information of the article: First Author; Year, Language and country of publication, the title of the article 2. Inclusion and exclusion criteria. 3. The baseline of the study: the number of study groups and center, the sample size, sex ratio, age, course 4. Interventions in the observation group and the control group 5. Outcome 6. Methodological quality and hence bias risk If there is any missing information in the literature, we will contact the lead author for further details. Any disagreement arising from this process will be resolved through discussion or a third reviewer.

**Quality assessment / Risk of bias analysis:** We will use the Cochrane Handbook for Systematic Reviews of Interventions

(Higgins 2011) to evaluate the quality of reviews. Evaluators cross-check the results, if the results are inconsistent, then we will resolve through internal discussion, or a third reviewer to re-assess.

**Strategy of data synthesis:** When there is sufficient similarity in the data, we will use RevMan5.1 software for analysis; conversely, we will use descriptive analysis. When the test is sufficiently similar, the heterogeneity test will be performed on the included studies by using chi-square test and  $I^2$  test to estimate the included studies. The p-value of the chi-square test is used to test the heterogeneity. If  $P < 0.01$ , there is heterogeneity; if  $P > 0.1$ , there is no obvious heterogeneity. And then we will use  $I^2$  to estimate the degree of heterogeneity. We define that: 0% -40% is mild heterogeneity, 30% -60% is moderate heterogeneity; 50% -90% is large heterogeneity; 75% -100% great heterogeneity. The count data will be represented by using relative risk (RR), while the continuous variables will be represented by standard mean differences (SMD). Both we will give a 95% confidence interval (CI). If there is heterogeneity between the interventions ( $I^2$  is greater than 50% or  $P < 0.1$ ), the stochastic effect model is used for calculation; otherwise, the fixed effect model is used.

**Subgroup analysis:** If the necessary data are available, subgroup analyses will be done for people with different translation ways and timepoint.

**Sensibility analysis:** We will preside over sensitivity analysis to identify the robustness and stability of study findings by excluding low quality trials.

**Language:** Unlimited.

**Country(ies) involved:** China.

**Other relevant information:** None.

**Keywords:** Electroacupuncture, spinal cord injury, motor function.

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**Dissemination plans:** We expect to present findings in writing to patients with spinal cord injury and their families and caregivers. We intend to publish the findings in a peer-reviewed journal (open-access if possible) and upload the manuscript accepted for publication to our university's institutional repository.

**Contributions of each author:**

**Author 1 - Jiuqing Tan - Establish projects, literature search, data analysis, writing papers.**

**Author 2 - Wenya Pei - Literature search, data analysis.**

**Author 3 - Baobao Zhang - Data extraction.**

**Author 4 - Xiaoqing Cen - Data extraction.**

**Author 5 - Guohua Lin - Coordinate the project and provide funds.**