

# INPLASY PROTOCOL

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## Efficacy and safety of heat-sensitive moxibustion in the treatment of neurogenic bladder after spinal cord injury: a protocol for systematic review and meta-analysis

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**Conflicts of interest:**  
None declared.

**Review question / Objective:** How about the efficacy and safety of heat-sensitive moxibustion in the treatment of neurogenic bladder after spinal cord injury.

**Condition being studied:** Neurogenic bladder(NB) is one of the common complications after spinal cord injury(SCI).Studies have shown that 80% of patients with SCI will develop into neurogenic bladders.Some studies suggest that heat-sensitive moxibustion can improve the bladder symptoms of patients with NB after SCI.Although heat-sensitive moxibustion can treat NB after SCI, there is no systematic review or meta-analysis to investigate its safety and effectiveness. Therefore, it is necessary to carry out a systematic review of the literatures concerning the safety and efficacy of heat-sensitive moxibustion for treatment of NB after SCI.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 18 May 2021 and was last updated on 18 May 2021 (registration number INPLASY202150071).

### INTRODUCTION

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improve the bladder symptoms of patients with NB after SCI. Although heat-sensitive moxibustion can treat NB after SCI, there is no systematic review or meta-analysis to investigate its safety and effectiveness. Therefore, it is necessary to carry out a systematic review of the literatures concerning the safety and efficacy of heat-sensitive moxibustion for treatment of NB after SCI.

## METHODS

**Participant or population:** All patients with neurogenic bladder after spinal cord injury (as diagnosed by a clinician, or using any recognized diagnostic criteria) will be included.

**Intervention:** Heat-sensitive moxibustion therapy, or mixed therapies based on heat-sensitive moxibustion will also be include.

**Comparator:** The control group was treated with conventional treatment or combined with other acupuncture except heat-sensitive moxibustion.

**Study designs to be included:** Clinical randomized controlled trials (RCTs) containing heat-sensitive moxibustion for NB after SCI 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, The Cochrane Library, China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang Database (WF), and Chinese Biomedical Literature Database (CBM). We will also trace the references of relevant studies to ensure that any potential eligible RCTs will not be missed.

**Main outcome(s):** Clinical efficacy including total effective rate and reported by

participants in a voiding diary (the mean number of urination and/or incontinence episodes per 24 hours, the number of participants with incontinence or retention, and the number of participants requiring catheterisation).

**Quality assessment / Risk of bias analysis:** The quality evaluation of the included study will be conducted by two researchers using Cochrane collaboration's tool, covering selection bias, performance bias, detection bias, attrition bias, reporting bias and other bias, each rated as low-risk, unclear and high-risk, and consulted a third reviewer when necessary. Two researchers will complete the process independently and a third researcher will be consulted if their evaluation results are inconsistent.

**Strategy of data synthesis:** The analysis will be done using Review Manager 5.3 Software. The heterogeneity between the included studies will be analyzed by Cochran's Q test and Higgins  $I^2$  statistic. If there is no statistical heterogeneity between the results of each study ( $P > 0.1$ ,  $I^2 < 50\%$ ), fixed-effect model will be used for meta analysis. Otherwise the source of heterogeneity will be further analyzed and random-effect model will be used after excluding the influence of obvious clinical heterogeneity. All outcomes will be analysed using 95% confidence intervals (95% CI).

**Subgroup analysis:** The heterogeneity test will be carried out first among all studies,  $I^2$  test will be used. When  $P > 0.1$  and  $I^2 < 50\%$ , the fixed effect model will be used; otherwise, the random effect model will be used. When the clinical heterogeneity between the two studies is large, only descriptive analysis will be performed.

**Sensitivity analysis:** The purpose of sensitivity analysis is to determine the sources and confounding factors of heterogeneity. If the trial data is sufficient, low or high quality studies will be excluded one by one for sensitivity analysis.

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

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**Keywords:** Heat-sensitive moxibustion; spinal cord injury; neurogenic bladder; systematic review; protocol.

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