INPLASY PROTOCOL

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

Conflicts of interest: **None.**

Efficacy of intrathecal baclofen bolus on neuropathic pain in patients with spinal cord injury: a protocol for systematic review and meta-analysis

Wang, SF[1]; Wang, ZM[2]; Song, WD[3]; Tang, ZC[4]; Chai, Y[5].

Review question / Objective: **Is intrathecal baclofen bolus (IBB) effective and safety on neuropathic pain (NPP) in patients with spinal cord injury (SCI)?**
Condition being studied: **Intrathecal baclofen bolus, neuropathic pain, and spinal cord injury.**
Information sources: **A comprehensive search will be conducted from the following electronic databases from their onset to the March 1, 2020: PubMed, EMBASE, Cochrane Library, Web of Science, Chinese Scientific Journal Database Information, WANGFANG, and China National Knowledge Infrastructure. We will not utilize any limitations of language and publication date to the literature search. The sample of search strategy for PubMed is presented. We will also adapt similar search strategies with specifics to other electronic databases. In addition to the above electronic databases, we will also check other resources, including dissertations and reference lists of qualified studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 April 2020 and was last updated on 27 April 2020 (registration number INPLASY202040192).

INTRODUCTION

Review question / Objective: **Is intrathecal baclofen bolus (IBB) effective and safety on neuropathic pain (NPP) in patients with spinal cord injury (SCI)?**

Condition being studied: **Intrathecal baclofen bolus, neuropathic pain, and spinal cord injury.**

METHODS

Participant or population: Any SCI patients who were diagnosed as NPP will be included in this study. No restrictions upon race, gender, age, severity and duration of SCI and NPP will be applied to this study.

Intervention: All patients in the experimental group underwent IBB alone as their management for NPP.

Comparator: All participants in the control group received any treatments, such as alternative medicine, massage, or any other interventions. However, we will exclude patients who also taken IBB.

Study designs to be included: This study will only include randomized controlled trials (RCTs) of IBB on NPP in patients with SCI.

Eligibility criteria: This study will only include RCTs of IBB on NPP in patients with SCI. Any other studies including quasi-RCTs will be excluded from this study.

Information sources: A comprehensive search will be conducted from the following electronic databases from their onset to the March 1, 2020: PubMed, EMBASE, Cochrane Library, Web of Science, Chinese Scientific Journal Database Information, WANGFANG, and China National Knowledge Infrastructure. We will not utilize any limitations of language and publication date to the literature search. The sample of search strategy for PubMed is presented. We will also adapt similar search strategies with specifics to other electronic databases. In addition to the above electronic databases, we will also check other resources, including dissertations and reference lists of qualified studies.

Main outcome(s): Primary outcome is pain intensity of NPP, as measured by Neuropathic Pain Symptom Inventory or any other relevant pain scales. Secondary outcomes are spasticity (as assessed by Modified Ashworth Scale or other associated scales), walking ability (as checked by 10 m-Walk Test or other tools), health-related quality of life (as identified by 36-Item Short Form Survey or other questionnaires), duration of stay at hospital (days), incidence of adverse event, and mortality rate.

Data management: Data will be collected from the included trials by two independent authors using an advance-designed data extraction sheet. Any inconsistencies will be resolved by discussion with another experienced author. We will collect data of title, first author, publication date, country, demographic characteristics of patients (such as age, sex, race, et al), trial setting, sample size, trial methods (such as randomization, blind, et al), interventions, comparators, outcome variables, results, findings, follow-up data, and conflict of interest.

Quality assessment / Risk of bias analysis: Two authors will independently appraise the quality of each eligible trial using the internationally recognized Cochrane risk of bias tool for assessing RCTs. It consists of 7 aspects, and each item is classified as low, unclear or high risk of bias. Any discrepancies will be solved by a third author, and consensus is reached.

Strategy of data synthesis: This study will use RevMan 5.3 software to conduct all statistical analysis. Continuous outcome values will be expressed as mean difference or standardized mean difference and 95% confidence intervals (CIs), and dichotomous outcome values will be explicated as risk ratio and 95% CIs. Statistical heterogeneity among qualified trials will be performed by I^2 statistics. $I^2 \leq 50\%$ suggests low heterogeneity, and a fixed-effects model will be used for synthesizing outcome data. $I^2 > 50\%$ states considerable heterogeneity, and a random-effects model will be employed for pooling outcome data. If sufficient data is collected and low heterogeneity is identified, we will carry out meta-analysis based on the similar study characteristics, types of interventions and controls, and outcome measurements. If significant heterogeneity is checked, we will perform subgroup

analysis to explore its possible reasons of the considerable heterogeneity.

Subgroup analysis: We will carry out subgroup analysis to find out possible reasons of the substantial heterogeneity according to the different types of treatments, controls, and outcome measurements.

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

Country(ies) involved: China.

Keywords: Intrathecal baclofen bolus; neuropathic pain; spinal cord injury; efficacy.