

INPLASY PROTOCOL

To cite: Liu et al. Can early surgery effectively treat incomplete cervical spinal cord injury? a protocol of systematic review. Inplasy protocol 202080081. doi: 10.37766/inplasy2020.8.0081

Received: 18 August 2020

Published: 19 August 2020

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Support: SXNF (2016JM8129)

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

Conflicts of interest: No.

Can early surgery effectively treat incomplete cervical spinal cord injury? a protocol of systematic review

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Review question / Objective: Can early surgery (ES) effectively treat incomplete cervical spinal cord injury (ICSCI)?

Condition being studied: Early surgery; incomplete cervical spinal cord injury.

Information sources: The following electronic databases will be pursued from the inauguration to the present: PUBMED, EMBASE, Cochrane Library, CINAHL, Scopus, Web of Science, and Chinese Biomedical Literature Database. In addition, we will check relevant conference or meeting abstracts, and reference lists of included trials to identify any potential studies. We will not implement any restrictions related to the language, publication date, and location. Only randomized controlled trials (RCTs) investigating the efficacy and safety of ES for ICSCI will be considered for inclusion. We will perform a rigorous search strategy using the key words comprising of spinal cord injury, incomplete injury, cervical, neck, injuries, trauma, early surgery, operation, surgical intervention, random, randomly, randomized controlled trials, controlled trial, clinical trial, blind, and allocation. Table 1 summarizes a detailed description of search strategy of PUBMED. Similar search strategies with details of other electronic databases will be adapted.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 19 August 2020 and was last updated on 19 August 2020 (registration number INPLASY202080081).

INTRODUCTION

Review question / Objective: Can early surgery (ES) effectively treat incomplete cervical spinal cord injury (ICSCI)?

Condition being studied: Early surgery; incomplete cervical spinal cord injury.

METHODS

Participant or population: Any participants with confirmed ICSCI in spite of race, age, gender, and duration and severity of the diseases, with or without comorbidities will be included.

Intervention: We will include any types of ES as an intervention treatment.

Comparator: As a control therapy, it could be any management, including oral medication, rehabilitation, acupuncture or any other interventions. However, we will exclude trials that utilized ES combined other treatments.

Study designs to be included: We will only include Randomized controlled trials (RCTs) of ES for patients with ICSCI. Laboratory studies, non-clinical studies, uncontrolled clinical trials, non-RCTs, and quasi-RCTs will be excluded. No restrictions of language and date of publication will be employed.

Eligibility criteria: We will only include RCTs of ES for patients with ICSCI. Laboratory studies, non-clinical studies, uncontrolled clinical trials, non-RCTs, and quasi-RCTs will be excluded. No restrictions of language and date of publication will be employed.

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operation, surgical intervention, random, randomly, randomized controlled trials, controlled trial, clinical trial, blind, and allocation. Table 1 summarizes a detailed description of search strategy of PUBMED. Similar search strategies with details of other electronic databases will be adapted.

Main outcome(s): Primary outcomes Spasticity (as measured by Spinal Cord Injury Assessment Tool or other relevant tools); Walking ability (as assessed by 10 m-Walk Test or other related tests); and Upper and lower extremity function (as evaluated by Modified Ashworth Scale or other connected scales). Secondary outcomes Hand dexterity and function (as checked by Box and Block test or Jebsen-Taylor hand function test or any other tests); Duration of hospital stay (days); Quality of life (as identified by World Health Organization Quality of Life-5 or other questionnaires); Complication rate; and Mortality rate.

Data management: Two authors will independently pull out related data from each qualified trial using a pre-designed standardized template form developed specifically for this study. Any doubts between two authors will be cleared up with the help of a third author through discussion or consultation. Data to be pulled out from included trials are as follows: Study characteristics: title, first author, date of publication, contact details, country, et al. Participants: age, gender, severity and duration of the symptoms, et al. Trial methods: details of randomization, blind, concealment, et al. Intervention and controls: types of treatments, number of sessions, dosage, frequency, et al. Outcomes: primary and secondary outcome measurements, and reported adverse events, et al. Others: findings, conflict of interest, et al.

Quality assessment / Risk of bias analysis: Two authors will independently carry out the assessment of risk of bias for each included trial using Cochrane risk of bias tool through 7 domains. For each field, risk of bias will be rated as low, unclear or high. Any conflicts between two authors will be

disentangled by a third author through discussion.

Contributions of each author:

Author 1 - Rui Liu.

Author 2 - Huan-jin Song.

Strategy of data synthesis: We will apply RevMan 5.3 software to synthesize and analyze the extracted data from included trials. We will demonstrate dichotomous values (e.g. complication rate, mortality rate) as risk ratio and 95% confidence intervals (CIs), and continuous values (e.g. spasticity, walking ability, upper and lower extremity function) as mean difference (MD) or standardized MD and 95% CIs. Statistical heterogeneity among eligible trials will be identified using I^2 test. We define $I^2 \leq 50\%$ as having acceptable heterogeneity, and a fixed-effects model will be employed to pool the data; while $I^2 > 50\%$ as indicating obvious heterogeneity, and a random-effects model will be manipulated to synthesize the data. If there are two or more studies for a specific category of intervention, meta-analyses will be conducted if the studies are sufficiently similar with respect to participants, interventions, comparator and outcomes. On the other hand, if heterogeneity is substantial, we will perform subgroup analysis to find out any possible sources of significant heterogeneity. If possible, we will undertake a narrative synthesis to analyze outcome data using a mixture of tables, and narrative report by the description and comparison of eligible studies.

Subgroup analysis: We will carry out subgroup analysis in accordance with the variations in study characteristics (e.g severity of ICSCI, duration of follow-up), study quality, details of treatments and comparisons.

Sensibility analysis: We will undertake sensitivity analysis to test the stability of study findings by removing low quality studies.

Country(ies) involved: China.

Keywords: Incomplete cervical spinal cord injury; early surgery; efficacy; safety.