INPLASY PROTOCOL

Hyperbaric oxygen therapy for spinal cord injury: A systematic review and meta-analysis

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Review question / Objective: P: spinal cord injury; I:Hyperbaric oxygen therapy; C:Conventional treatments such as surgery, drugs and rehabilitation physiotherapy; O:1.Primary outcomes: (1)American Spinal Injury Association(ASIA) Score: Includes American Spinal Injury Association Impairment Scale (AIS) and Asia Motor Score (AMS), (2)Frankel Classification Grading System, (3)Functional Independence Measure (FIM), (4)Barthel Index; 2.Secondary outcomes: (1)Hospitalization Time, (2)Death Rate, (3)Incidence of Any Expected or Unexpected Adverse Event, (4)Hamilton Anxiety Rating Scale (HAM-A), (5)Hamilton Depression Rating Scale (HAM-D); S:RCT.

Condition being studied: Hyperbaric oxygen (HBO) therapy can prevent further spinal cord injury (SCI) caused by spinal cord ischemia-reperfusion injury to the maximum extent, which has been reported increasingly in recent years. However its security and effectiveness still lack of high-quality evidence-based medical evidence. In this study, we will perform a systematic review of previously published randomized controlled trials to evaluate the efficacy and safety of HBO therapy for SCI.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 22 October 2020 and was last updated on 22 October 2020 (registration number INPLASY2020100084).

INTRODUCTION

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METHODS

Participant or population: Any adult patients(≥18 years) diagnosed with SCI will be included in this study regardless their ethnicity, sex, age, and the length and severity of disease.

Intervention: The experimental group is hyperbaric oxygen therapy combined with conventional treatments such as surgery, drugs and rehabilitation physiotherapy.

Comparator: The control group received conventional treatments such as surgery, drugs and rehabilitation physiotherapy.

Study designs to be included: Randomized controlled trials (RCTs) will be included in this systematic review regardless of publication status and language.

Eligibility criteria: Randomized controlled trials (RCTs) will be included in this systematic review regardless of publication status and language.

Information sources: PubMed, Embase, Cochrane Library, Web of Science, China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang database and Chinese Biomedical Literature Database (CBM).

Main outcome(s): (1)American Spinal Injury Association(ASIA) Score: Includes American Spinal Injury Association Impairment Scale (AIS) and Asia Motor Score (AMS) (2)Frankel Classification Grading System (3)Functional Independence Measure (FIM) (4)Barthel Index.

Additional outcome(s): (1)Hospitalization Time (2)Death Rate (3)Incidence of Any Expected or Unexpected Adverse Event (4)Hamilton Anxiety Rating Scale (HAM-A) (5)Hamilton Depression Rating Scale (HAM-D).

Quality assessment / Risk of bias analysis: Two contributors will perform quality assessments and review the risk of bias using the Cochrane Collaboration's risk-of-bias assessment method (v6)[36]. This scale includes 7 risk of bias items, and each will be described as low, unclear, or high risk. Data will be presented in the risk of bias graph. Discrepancies will be resolved or as required, by a third reviewer.

Strategy of data synthesis: We will employ RevMan 5.3 (Cochrane Community, London, UK) software to synthesize and analyze the data, and to perform a meta-analysis if possible. If acceptable heterogeneity is examined among included trials, we will conduct a meta-analysis in accordance with the few variations in study and patient characteristics, and few differences in treatments, controls, and outcomes. If considerable heterogeneity is identified, we will carry out subgroup analysis and sensitivity analysis to find out any possible sources of obvious heterogeneity. If it is impossible to undertake a meta-analysis, we will report study results as a narrative summary.

Subgroup analysis: We will observe the source of considerable heterogeneity by subgroup analysis based on variations in study and patient characteristics, study

quality, different interventions, comparators, and outcomes.

Sensibility analysis: We will perform sensitivity analysis to test the robustness and satiability of conclusions by removing low quality trials, and trials with small sample size.

Country(ies) involved: China.

Keywords: Spinal Cord Injury, Hyperbaric Oxygen Therapy, Meta-Analysis, Protocol.

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