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 extracorporeal shock wave combined spinal core decompression for the treatment of patients with femoral head necrosis: a protocol for systematic review and meta-analysis

Qiao, XF[1]; Liu, SC[2]; Xue, Y[3]; Ji, QH[4].

Review question / Objective: **Does extracorporeal shock wave (EPSW) combined spinal core decompression (SCD) effective for the treatment of patients with femoral head necrosis (FHN)?**
Condition being studied: **Extracorporeal shock wave; spinal core decompression; femoral head necrosis.**
Information sources: **We will systematically search MEDLINE, Web of Science, Scopus, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge In¬frastructure. We will search each electronic database from inception through March 1, 2020 without language and publication date limitations. This study will only consider RCTs that explored the efficacy and safety of EPSW and SCD for the treatment of patients with FHN. The search strategy for MEDLINE is created. We will also build similar search strategies for other electronic databases. In addition, we will also investigate other literature sources to avoid missing potential studies, such as conference abstracts and reference lists of related reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2020 and was last updated on 15 April 2020 (registration number INPLASY202040092).

INTRODUCTION

Review question / Objective: **Does extracorporeal shock wave (EPSW) combined spinal core decompression (SCD) effective for the treatment of patients with femoral head necrosis (FHN)?**
Condition being studied: **Extracorporeal shock wave; spinal core decompression; femoral head necrosis.**

METHODS

Participant or population: We will include patients who were diagnosed with FHN, regardless their country, race, gender, and duration and severity of FHN.

Intervention: In the experimental group, all patients must receive EPSW combined SCD therapy alone. Any combination therapies with EPSW or/ and SCD will be excluded.

Comparator: In the control group, all participants could undergo any treatments without limitations. However, we will exclude studies that involved treatments of EPSW or/ and SCD.

Study designs to be included: We will include randomized controlled trials (RCTs) that evaluated the efficacy and safety of EPSW and SCD for the treatment of patients with FHN.

Eligibility criteria: This study will compare the efficacy and safety of EPSW and SCD with other therapies for the treatment of patients with FHN.

Information sources: We will systematically search MEDLINE, Web of Science, Scopus, EMBASE, Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge In¬frastructure. We will search each electronic database from inception through March 1, 2020 without language and publication date limitations. This study will only consider RCTs that explored the efficacy and safety of EPSW and SCD for the treatment of patients with FHN. The search strategy for MEDLINE is created. We will also build similar search strategies for other electronic databases. In addition, we will also investigate other literature sources to avoid missing potential studies, such as conference abstracts and reference lists of related reviews.

Main outcome(s): Primary outcome is pain intensity (assessed by any pain scales, such as Numerical Rating Scale). Secondary outcomes are pain, stiffness, and physical function of attacked knee and hip joints (as measured by Western Ontario and McMaster Universities Osteoarthritis Index or other relevant tools); and health-related quality of life (as identified by 36-Item Short Form Health Survey or other related scores), and adverse events.

Data management: Two independent authors will extract data utilizing predefined data acquisition sheet. Any discrepancies between two authors will be resolved by a third author through consultation, and a consensus will be reached. The sheet includes study characteristics (e.g. study ID, time of publication, country, et al), study population (e.g. country, age, inclusion and exclusion criteria, et al), study design (e.g. sample size, details of randomization, blind, et al), intervention and comparison (e.g. treatment types, dosage, frequency, et al), outcomes, safety, results, findings, and other related information.

Quality assessment / Risk of bias analysis: Risk of bias for all included RCTs will be appraised by two independent authors using Cochrane Risk of Bias Tool. Each study will be evaluated through 7 aspects and each criteria will be valued as low, unclear or high risk of bias. Differences between two authors will be settled through consensus with the help of a third author.

Strategy of data synthesis: We will use RevMan 5.3 software to analyze the data, and to perform a meta-analysis if necessary. Any dichotomous data (such as incidence of adverse events) will be calculated as risk ratio and 95% confidence intervals (CIs), and any continuous data (such as pain intensity) will be rated as mean difference or standardized mean difference and 95% CIs. Statistical heterogeneity will be checked using I^2 test. $I^2 \leq 50\%$ suggests little or no statistical heterogeneity, and we will employ a fixed-effects model. If sufficient trials are included with little or no statistical heterogeneity, we will consider conducting a meta-analysis. $I^2 > 50\%$ means obvious heterogeneity, and we will place a random-

effects model. A subgroup analysis will be performed to investigate possible sources of remarkable heterogeneity. If necessary, we will also carry out a narrative summary.

Subgroup analysis: If sufficient data is available, a subgroup analysis will be conducted to identify the sources of obvious heterogeneity according to the differences in study and patient characteristics, types of interventions and comparators, and outcomes.

Sensibility analysis: A sensitivity analysis will be carried out to examine the robustness of the study findings according to the methodological weaknesses and missing data.

Country(ies) involved: China.

Keywords: Femoral head necrosis; extracorporeal shock wave; spinal core decompression; efficacy.