INPLASY PROTOCOL

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

Conflicts of interest: **No.**

High-energy extracorporeal shock wave therapy for early stage femoral head osteonecrosis: a protocol of systematic review

Ji, QH[1]; Liu, SC[2]; Miao, J[3]; Ren, ZX[4]; Yuan, YF[5]; Li, YB[6].

Review question / Objective: **Does high-energy extracorporeal shock wave therapy (HEEPSWT) effectively and safely treat early stage femoral head osteonecrosis (ESFHO)?**
Condition being studied: **Extracorporeal shock wave; osteonecrosis.**
Information sources: **We will identify the following electronic databases from conception to the present: Cochrane Library, EMBASE, PUBMED, Web of Science, Cumulative Index to Nursing and Allied Health Literature, VIP database, and China National Knowledge Infrastructure. No limitation will be applied to language and publication status. We will consider any potential RCTs that investigated the effectiveness and safety of HEEPSWT for ESFHO. The sample of search strategy for Cochrane Library is crated. Similar search strategy with details will also be built for other electronic databases. In addition, we will search dissertations, conference abstracts, and reference lists of any relevant reviews to avoid missing any potential literature.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 14 June 2020 and was last updated on 14 June 2020 (registration number INPLASY202060055).

INTRODUCTION

Review question / Objective: **Does high-energy extracorporeal shock wave therapy (HEEPSWT) effectively and safely treat early stage femoral head osteonecrosis (ESFHO)?**

Condition being studied: **Extracorporeal shock wave; osteonecrosis.**

METHODS

Participant or population: **This study will fully consider patients who were clinically diagnosed as ESFHO for inclusion**

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inconsiderate their country, race, sex, and age.

Intervention: In the experimental group, all subjects underwent single HEEPSWT intervention as their solely management.

Comparator: In the control group, all patients received any treatments, but not any forms of HEEPSWT, will be included.

Study designs to be included: We will include all potential randomized controlled trials (RCTs) focusing on the effectiveness and safety of HEEPSWT for ESFHO.

Eligibility criteria: We will include all potential RCTs focusing on the effectiveness and safety of HEEPSWT for ESFHO in spite of language and publication status. We will exclude any other studies, such as animal studies, case report, case series, reviews, comments, non-clinical trials, non-controlled trials, and non-RCTs.

Information sources: We will identify the following electronic databases from conception to the present: Cochrane Library, EMBASE, PUBMED, Web of Science, Cumulative Index to Nursing and Allied Health Literature, VIP database, and China National Knowledge Infrastructure. No limitation will be applied to language and publication status. We will consider any potential RCTs that investigated the effectiveness and safety of HEEPSWT for ESFHO. The sample of search strategy for Cochrane Library is crated. Similar search strategy with details will also be built for other electronic databases. In addition, we will search dissertations, conference abstracts, and reference lists of any relevant reviews to avoid missing any potential literature.

Main outcome(s): Primary outcome - Pain intensity of hip or knee joints (as assessed by Numerical Rating Scale or any other pain scales). Secondary outcomes - Functional status and limitation of hip or knee joints (as evaluated by Western Ontario and McMaster Universities Osteoarthritis Index or other related indexes); Health-related quality of life (as identified by 12-Item Short-Form Health Survey or other connected tools); and Adverse events.

Data management: Two independent researchers will extract data from each eligible trial using a predefined standardized data extraction form. The extracted data comprises of reference identification, author information, patient characteristics, study design, sample size, study methods, details of interventions and comparators, endpoints at different time points, results, findings, adverse events, conflict of interests, and funding information. Any disagreements will be figured out via discussion with the help of a third researcher.

Quality assessment / Risk of bias analysis: Study quality of each included trial will be estimated based on the guidelines of Cochrane Risk of Bias Tool by two independent researchers. It comprises of 7 specific fields, and each one is further rated as low risk of bias, unclear risk of bias, and high risk of bias. Any differences in assessment will be resolved through consultation or discussion with the help of another researcher.

Strategy of data synthesis: Results regarding the pain intensity, functional status, limitation of knee or hip joints, and health-related quality of life, the outcome data will be expressed as mean difference, or standardized mean difference and 95% confidence intervals (CIs). Regarding the incidence of adverse events, it will be calculated as risk ratio and 95% CIs. The extent of statistical heterogeneity is investigated with I^2 test. If $I^2 \leq 50\%$, we will estimate minor or low heterogeneity. If $I^2 > 50\%$, we will estimate significant heterogeneity. If sufficient data will be collected with minor heterogeneity across the trials, we will undertake a meta-analysis according to the similar conditions of study and patient characteristics, specifics of interventions and controls, and outcome measurements. If we find significant heterogeneity across the studies, we will perform a subgroup analysis. If the meta-analysis is deemed not

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to be conducted, we will present outcome results as a narrative summary.

Subgroup analysis: We will perform subgroup analysis to identify any possible sources of substantial heterogeneity based on the variations in characteristics, different treatments, controls, outcome measurements.

Sensibility analysis: We will conduct sensitivity analysis to examine the robustness of the merged outcomes by removing trials with low quality.

Country(ies) involved: China.

Keywords: Extracorporeal shock wave; high-energy; femoral head; osteonecrosis.

Contributions of each author:
Author 1 - Qing-hui Ji.
Author 2 - Shi-chen Liu.
Author 3 - Jie Miao.
Author 4 - Zhi-xin Ren.
Author 5 - Yu-fei Yuan.
Author 6 - Yan-bao Li.

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