INPLASY PROTOCOL

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Conflicts of interest:
None.

Efficacy of four hollow nail rhombic fixation for the treatment of patients with femoral neck fractures: a protocol of systematic review and meta-analysis

Ji, QH[1]; Xue, Y[2]; Miao, J[3]; Reng, ZX[4]; Yuan, YF[5]; Li, YB[6].

Review question / Objective: **Is four hollow nail rhombic fixation (FHNRF) effective and safety for the treatment of patients with femoral neck fractures (FNF)?**
Condition being studied: **Femoral neck fractures; four hollow nail rhombic fixation.**
Information sources: **We will systematically and comprehensively conduct searches in MEDLINE, Scopus, Web of Science, EMBASE, Cochrane Library, ProQuest, Thesis and Dissertation Catalog, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge Infrastructure from inception through February 29, 2020 with no restrictions to the language and publication date. We will consider all potential RCTs that explored the efficacy and safety of FHNRF for the treatment of patients with FNF. The full search strategy for MEDLINE is displayed, and we will also adapt similar search strategies for other electronic databases. We will identify other sources to avoid losing potential studies, such as dissertations/thesis, conference proceedings and reference lists of included RCTs.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 April 2020 and was last updated on 17 April 2020 (registration number INPLASY202040106.

INTRODUCTION

Review question / Objective: **Is four hollow nail rhombic fixation (FHNRF) effective and safety for the treatment of patients with femoral neck fractures (FNF)?**

Condition being studied: **Femoral neck fractures; four hollow nail rhombic fixation.**

METHODS

Participant or population: **All patients who were diagnosed with FNF will be included, in spite of their characteristics, and duration and severity of FNF.**

Intervention: All patients in the interventional group received FHNRF as their therapy.

Comparator: Studies comparing any other treatments, such as partial hip replacement, and total hip replacement will be included in this study.

Study designs to be included: All randomized controlled trials (RCTs) that appraised the efficacy and safety of FHNRF for the treatment of patients with FNF will be included.

Eligibility criteria: All RCTs that appraised the efficacy and safety of FHNRF for the treatment of patients with FNF will be included. We will exclude all other studies, such as laboratory studies, case report, case series, review, and non-clinical trial.

Information sources: We will systematically and comprehensively conduct searches in MEDLINE, Scopus, Web of Science, EMBASE, Cochrane Library, ProQuest, Thesis and Dissertation Catalog, Cumulative Index to Nursing and Allied Health Literature, and China National Knowledge Infrastructure from inception through February 29, 2020 with no restrictions to the language and publication date. We will consider all potential RCTs that explored the efficacy and safety of FHNRF for the treatment of patients with FNF. The full search strategy for MEDLINE is displayed, and we will also adapt similar search strategies for other electronic databases. We will identify other sources to avoid losing potential studies, such as dissertations/thesis, conference proceedings and reference lists of included RCTs.

Main outcome(s): The primary outcome is pain intensity, which has been assessed by any relevant pain scales, such as Visual Analogue Scale. The secondary outcomes are stiffness and physical function (as examined by any associated index, such as Western Ontario and McMaster Universities Osteoarthritis Index); and quality of life (as assessed by any related scales, such as 36-Item Short Form Health Survey), and adverse events.

Data management: Two examiners will independently extract data from eligible studies. The extracted information includes trial setting, trial characteristics (e.g. first author, time of publication, et el), research design, details of intervention and comparator, eligibility criteria, outcomes, patient characteristics (e.g. sample size, sex, age, comorbidities, et al), results, conclusion and conflict of interest. Any discrepancies will be solved through discussion with a third examiner.

Quality assessment / Risk of bias analysis: Two examiners will separately identify risk of bias for each eligible study using Cochrane Risk of Bias Tool. It assesses risk of bias through 7 aspects and each one is graded as low, unclear or high risk of bias. Opposite opinions will be arbitrated by a third examiner through discussion.

Strategy of data synthesis: We will place RevMan 5.3 software to analyze extracted data, and carry out a meta-analysis whenever possible. We will estimate the pooled treatment effects of dichotomous data as risk ratio and 95% confidence intervals (CIs), and those of continuous data as weighted mean difference or standardized mean difference and 95% CIs. We will check statistical heterogeneity across RCTs by I^2 test. $I^2 \leq 50\%$ exerts little statistical heterogeneity, and a fixed-effects model will be applied. $I^2 > 50\%$ indicates distinct heterogeneity, and a random-effects model will be employed. A subgroup analysis will be conducted to test possible reasons of apparent heterogeneity. If there is still evident heterogeneity after subgroup analysis, we will conduct a narrative summary.

Subgroup analysis: We will carry out a subgroup analysis to explore the sources of obvious heterogeneity based on the different types of study and patient characteristics, interventions and comparators, and outcomes.

Sensibility analysis: We will perform a sensitivity analysis to test the robustness of study findings based on the methodological weaknesses and missing data.

Country(ies) involved: China.

Keywords: Femoral neck fractures; four hollow nail rhombic fixation; efficacy; safety