

Traditional Chinese medicine treatment of postoperative delirium after hip fracture : A systematic review protocol

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ADMINISTRATIVE INFORMATION

Support - Tutor topic : Objective quantitative evaluation of TCM syndrome differentiation of primary osteoporosis based on three-dimensional gait analysis (2021FSYYZZ14).

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

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023120094

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 December 2023 and was last updated on 24 December 2023.

INTRODUCTION

Review question / Objective This study aims to provide comprehensive evidence of high quality of TCM treatment for POD of hip fracture from incidence of delirium, delirium severity, duration and length of hospitalization.

Condition being studied Postoperative delirium(POD) is a common complication in patients with hip fracture surgery. Traditional Chinese Medicine (TCM) has been proved to be effective in the treatment of hip fracture POD by a number of studies. The purpose of this study is to evaluate the efficacy and safety of TCM in the treatment of POD in hip fracture, and to provide the latest evidence for clinical application.

METHODS

Participant or population Regardless of the subtype of hip fracture POD, all participants

diagnosed with hip fracture POD will get attention. There are no restrictions on gender, age, race, economic status or education level.

Intervention Studies will be included if the intervention group was treated with TCM decoction orally. There will be no restrictions on the the specific prescription and decoction method. Studies will be included if the intervention group was treated with TCM decoction orally. There will be no restrictions on the the specific prescription and decoction method. At the same time, Studies that describe treatments focused on the prevention of no treatment, routine west medicine treatment, and placebo treatment will be excluded.

Comparator Studies that describe treatments focused on the prevention of no treatment, routine west medicine treatment, and placebo treatment will be excluded.

Study designs to be included RCT.

Eligibility criteria A prospective randomized controlled trials (RCTs) of TCM dealing with POD of hip fracture POD will be included in this review, whether using blind method or allocation concealment method. The courtroom language is limited to Chinese and English. Non-randomized controlled trials, a series of case reports and cross-over studies were excluded.

Information sources The following databases will be searched : PubMed, MEDLINE, EMBASE, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Data, Chinese Science Journal Database (VIP) and Chinese Biomedical Literature Database (CBM). We will select eligible studies published up to December 30,2023. The search terms used in the systematic review are as follows : traditional Chinese medicine, postoperative delirium, and postoperative disturbance of consciousness. We do not apply any language, population or national restrictions.

Main outcome(s) Incidence of delirium will be used as the main outcome of POD in hip fracture. Delirium will be diagnosed using validated assessment methods of delirium (e.g., CAM, ICU-CAM or 3D-CAM).

Additional outcome(s) We also focus on the following indicators :delirium severity, duration and length of hospitalization. In addition, we will carefully observe the adverse reactions of patients in the process of oral Chinese medicine.

Quality assessment / Risk of bias analysis Two reviewers will use the Cochrane Collaboration tool to assess the quality of each article to assess the risk of bias[16]The evaluation includes generating random sequences, allocation concealment, deceiving subjects and personnel, incomplete outcome data, selective outcome reporting, and other sources of bias. According to the standard, it is divided into low risk, high risk and unclear. Two evaluators will independently participate in the evaluation of each study, and any differences will be resolved through discussion.

Strategy of data synthesis Revman V.5.4 will be used for data synthesis and analysis. When the heterogeneity of the statistical description is not obvious, the evaluator implements a fixed effect model. Instead, a random effects model will be used to detect the sources of statistical heterogeneity. If the heterogeneity is significant, researchers can turn to subgroup or sensitivity

analysis, and $\alpha = 0.05$ is used to evaluate the meta-analysis.Two reviewers will independently retrieve data based on a pre-designed data collection form and use a spreadsheet to extract the following information : study details (first author name or newsletter, publication time, year of publication, multicenter study or non-study), subject details (baseline data, diagnostic criteria for delirium after hip fracture surgery, exclusion criteria, gender, year) age, method used (sample size, blindness, distribution concealment), intervention in the treatment group and the control group, primary and secondary results (incidence of delirium,delirium severity, duration and length of hospitalization, adverse events). If the data mentioned above is incomplete, we will contact the author of the article. All reviewers will be involved in the discussion to resolve discrepancies if necessary.

Subgroup analysis When meta-analysis shows significant heterogeneity, we will perform subgroup analysis based on the type of postoperative delirium and different Chinese herbal prescriptions.

Sensitivity analysis Sensitivity analysis will be used to test the quality of the studies included in the sampling files. The stability of the conclusion can be tested by re-analysing the conclusion by inputting missing data and changing the type of study.

Language restriction The courtroom language is limited to Chinese and English.

Country(ies) involved China.

Keywords traditional Chinese medicine, postoperative delirium, hip fracture, systematic review, meta-analysis.

Contributions of each author

Author 1 - Zhou Jie - The author put forward the concept, early manuscripts, retrieved the literature, and revised the manuscript.

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Author 2 - Qian Chenhui - The author made a survey and provided statistical expertise.

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