INPLASY PROTOCOL

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

Conflicts of interest: **No.**

Effect of Xingnaojing injection for the treatment of acute alcoholism: a protocol of systematic review and meta-analysis

Wu, X[1]; Yang, LJ[2]; Gao, P[3]; Qiao, ZL[4]; Xu, D[5]; Zhang, FH[6].

Review question / Objective: **Does Xingnaojing injection (XNJI) effectively treat acute alcoholism (AAH)?**
Condition being studied: **Xingnaojing injection, and acute alcoholism.**
Information sources: **Electronic databases - All potential studies will be sought in electronic databases (MEDLINE, EMBASE, Cochrane Library, China National Knowledge Infrastructure Database, Wan fang Database, and VIP Science Technology Periodical Database) from inception to the April 1, 2020. There are no limitations related to the language and publication time. The search strategy sample for MEDLINE will be showed in table 1. Similar search strategy sample for other electronic databases will be adapted. Searching other resources - This study will also search other resources, such as thesis, dissertations, conference papers 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 27 April 2020 and was last updated on 27 April 2020 (registration number INPLASY202040197).

INTRODUCTION

Review question / Objective: **Does Xingnaojing injection (XNJI) effectively treat acute alcoholism (AAH)?**

Condition being studied: **Xingnaojing injection, and acute alcoholism.**

METHODS

Participant or population: **All patients who were diagnosed as AAH will be included in this study, irrespective age, race, gender, and nationality.**

Intervention: **All patients underwent XNJI for the treatment of AAH will be included in this study.**

Comparator: All patients received any management for the treatment of AAH will be considered for inclusion. However, any studies involved XNJI as a control therapy will be excluded.

Study designs to be included: This study will include randomized controlled trials (RCTs) that explored the effect of XNJI for the treatment of AAH.

Eligibility criteria: This study will include randomized controlled trials (RCTs) that explored the effect of XNJI for the treatment of AAH. We will exclude other studies, such as animal studies, observational studies, review, and uncontrolled studies.

Information sources: Electronic databases - All potential studies will be sought in electronic databases (MEDLINE, EMBASE, Cochrane Library, China National Knowledge Infrastructure Database, Wan fang Database, and VIP Science Technology Periodical Database) from inception to the April 1, 2020. There are no limitations related to the language and publication time. The search strategy sample for MEDLINE will be showed in table 1. Similar search strategy sample for other electronic databases will be adapted. Searching other resources - This study will also search other resources, such as thesis, dissertations, conference papers and reference lists of related reviews.

Main outcome(s): Primary outcomes include time to wake up, time to symptoms disappeared, time to cognitive function recovery, and time to motor function recovery. Secondary outcomes consist of Glasgow coma score, neurological deficit score, emergency observation time, time to return normal systolic blood pressure, time to recover normal breathing, time to recover normal temperature, serum interleukin-6, tumor necrosis factor- α, C-reactive protein, and incidence of adverse reactions.

Data management: Two reviewers will independently extract data using a predefined data extraction form. Any divisions between two reviewers will be solved by a third reviewer through discussion. The extracted information consists of study information (e.g. title, primary authors, time of publication), patient information (e.g. sex, age, diagnostic criteria, and eligibility criteria), study methods, treatment and control specifics, outcome indicators, results, findings, and conflict of interest. Any insufficient or missing data will be required from original trial authors by email, fax or telephone.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess the risk of bias for each trial using Cochrane risk of bias tool. This tool covers seven domains and each aspect is further rated as high, unclear or low risk of bias. Discrepancies between two reviewers will be solved through discussion with the help of a third reviewer.

Strategy of data synthesis: This study will employ RevMan 5.3 software for statistical analysis. If the trials are homogeneous and the data are similar and synthesizable, we will conduct a meta-analysis according to the study information, patient characteristics, details of interventions and controls, and outcome indicators. On the other hand, if we detect obvious heterogeneity, we will carry out a subgroup analysis and meta-regression test to investigate the sources of remarkable heterogeneity.

Subgroup analysis: We will carry out a subgroup analysis to examine obvious heterogeneity according to the different types of study characteristics, details of treatments and comparators, and outcome indicators.

Sensibility analysis: We will undertake a sensitivity analysis to examine the robustness of merged outcome results by removing trials with low quality.

Country(ies) involved: China.

Keywords: Acute alcoholism; Xingnaojing injection; effect; safety.