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Efficacy of Salviae miltiorrhizae and ligustrazine hydrochloride injection on NIHSS, activity of daily living, hemorheology and blood lipid indexes in patients with acute ischemic stroke: a protocol for systematic review and meta analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 08 May 2024 and was last updated on 08 May 2024.

INTRODUCTION

Review question / Objective The purpose of this study was to investigate the effects of Danshen hydrochloride tetramethylpyrazine injection on NIHSS, daily living ability, hemorheology and lipid indexes in patients with acute ischemic stroke.

Rationale The laboratory is well equipped with first-class experimental instruments and tools, which provides strong support for scientific research and experimental work. First of all, the laboratory is equipped with various types and specifications of experimental equipment, which can meet the needs of different disciplines and experimental projects. Laboratory equipment is not only abundant, but also diverse, able to meet a variety of needs from basic experiments to advanced research. The team is complete and has an efficient, professional and diversified team, which provides a solid human resources guarantee for the smooth progress of the project. The team members have specialized skills and knowledge in their respective fields, covering all levels from basic research to project management. They are not only deeply knowledgeable in their field, but also able to communicate and collaborate effectively with other members.

Condition being studied Salviae miltiorrhizae and ligustrazine hydrochloride injection (SMLHI), a kind of Chinese herbal medicine injection, has been considered as a promising supplementary treatment for acute ischemic stroke (AIS). However, its clinical efficacy is still not well investigated. In this study, the randomized controlled trials (RCTs) of SMLHI for the treatment of AIS were systematically reviewed to evaluate its clinical efficacy and safety.

METHODS

Search strategy To perform a comprehensive and focused search, experienced systematic review investigators will be invited to develop a search strategy. The plan searched terms are as follows: "Danshen Chuanqiongqin" or "Danshen Chuanqiongqin injection" or "Salviae Miltiorrhizae and Ligustrazine" or "Radix Salivae Miltiorrhizae Ligustrazine injection" or "Salvia Miltiorrhiza Ligustrazine injection" or "Salviae Miltiorrhizae and Ligustrazine Hydrochloride injection" combined with "ischemic stroke" or "acute ischemic stroke" or "cerebral infarction" or "acute cerebral infarction" or "brain infarction" or "infarction of the brain" or "AIS" et al. example of search strategy for PubMed database shown in Table 1 will be modified and used for the other databases.

Participant or population Research subjects (patients with AIS) must meet WHO diagnostic criteria of AIS and exclude cerebral hemorrhage by brain computerized tomography (CT) or magnetic resonance imaging (MRI). No restrictions regarding age, gender, racial, region, education and economic status in this analysis.

Intervention AIS patients in the experimental group must be treated with conventional treatment combined with SMLHI.

Comparator In the control group, AIS patient treated with the same conventional treatment as experimental group.

Study designs to be included This systematic review and meta-analysis will be performed to systematically evaluate the efficacy of SMLHI on NIHSS, ADL, hemorheology and blood lipid indexes in patients with AIS.

Eligibility criteria Eligibility criteria - Types of studies. All available randomized controlled trials (RCTs) that investigated the efficacy of SMLHI on NIHSS, ADL, hemorheology and blood lipid indexes in patients with AIS will be included in this systematic review.
Types of participants. Research subjects (patients with AIS) must meet WHO diagnostic criteria of AIS and exclude cerebral hemorrhage by brain computerized tomography (CT) or magnetic resonance imaging (MRI). No restrictions regarding age, gender, racial, region, education and economic status in this analysis.
Types of interventions. AIS patients in the experimental group must be treated with conventional treatment combined with SMLHI.
Comparator. In the control group, AIS patient treated with the same conventional treatment as experimental group.
Exclusion criteria. Papers without sufficient available data, non-peer reviewed studies, non-RCTs, literature reviews, meta-analysis, meeting abstracts, case reports, commentaries, letter to the editor, and experimental model researches will be excluded from analysis.

Information sources Electronic databases including Google Scholar, PubMed, Cochrane Library, Medline, Excerpt Medica Database (Embase), Web of Science (WOS), Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (CSJ) and Wanfang Database will be systematically searched for eligible clinical trials from their inception to December 2023.

Main outcome(s) NIHSS; ADL as evaluated by BI score.Hemorrheology indexes, including whole blood viscosity (WBV), plasma viscosity (PV), whole blood high-shear viscosity (WBHSV), whole blood low-shear viscosity (WBLSV), content of fibrinogen (Fig), hematocrit (Hct) and platelet aggregation rate (PAR); The blood lipid indicators [Plasma total cholesterol (TC), triglycerides (TG), high density lipoprotein-cholesterol (HDL-C); low density lipoprotein-cholesterol (LDL-C)].

Additional outcome(s) Overall response rate (ORR); The Serum C-reactive protein (CRP) level; Treatment related adverse events.

Data management Two authors (CHZ and MM) will be responsible for the data extraction independently according to the Cochrane Handbook for Systematic Reviews of Intervention. Disagreements were adjudicated by a third reviewer (DG).
The following data will be extracted from eligible literatures:
Study characteristics and methodology: name of the first author, country of study, the first author, year of publication, number of cases, periods of data collection, and study parameter types, et al.
Participant characteristics: age, gender, ethnicity, inclusion and exclusion criteria, et al.
Interventions: therapeutic means, manufacturer of the drugs, dosage of SMLHI, administration route and cycles, duration of treatment and follow-up time, et al.
Outcomes measures and other parameters: ORR, NIHSS, BI, Hemorrheology indexes (WBV, PV, WBHSV, WBLSV, Fig, Hct and PAR) and blood lipid

indicators (TC, TG, HDL-C and LDL-C), CRP, and adverse effects.

Quality assessment / Risk of bias analysis Two investigators (WWZ and TL) will independently assess the methodological quality of the included RCTs by using the following criteria described in the Cochrane Handbook for Systematic Reviews of Interventions: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias.27,28 Evidence quality will be classified as low risk, high risk, or unclear risk of bias. Any disagreements will be resolved via discussion with a third reviewer (QRS).

Strategy of data synthesis Stata 14.0 (Stata Corp., College Station, TX, USA) and Review Manager 5.3 (Nordic Cochran Centre, Copenhagen, Denmark) statistical software will be used to pool the data and carry out the data analysis. Dichotomous data were represented by the risk ratio (RR) with the respective 95% confidence interval (CI), whereas continuous variables were expressed as standardized mean difference (SMD) with their 95% CI. A two-tailed $P < 0.05$ was considered statistically significant.

Subgroup analysis Subgroup and meta-regression analysis will be conducted to investigate the influence of treatment period, dose of SMLHI, level of risk of bias, and other unpredictable factors on clinical efficacy.

Sensitivity analysis Sensitivity analysis will be carried out to assess the reliability and robustness of the pooled results via eliminating trials with low quality. A summary table will report the results of the sensitivity analyses.

Language restriction No.

Country(ies) involved China.

Other relevant information No.

Keywords Salviae miltiorrhizae and ligustrazine hydrochloride injection, acute ischemic stroke, efficacy, meta-analysis.

Contributions of each author

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