INPLASY PROTOCOL

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Review Stage at time of this submission: Formal screening of search results against eligibility criteria.

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A systematic review of the therapeutic efficacy of Bushen prescription for ischemic stroke based on the theory " curing the brain from the Shen "

Li, X[1]; Xie, L[2]; Lin, X[3]; Hu, G[4].

Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy of "tonifying kidney and replenishing lean pulp" method in the treatment of neurological function defects after ischemic stroke. Could the use of the therapy improve NIHSS and ADL in patients with ischemic stroke?

Condition being studied: Current treatment methods for ischemic stroke are still very limited, and there is great need to exploit new ideas. Traditional Chinese medicine interventions has played an important role in stroke treatment. The therapeutic goal is to improve clinical symptoms and quality of life in patients with ischemic stroke. It has been shown that the "tonifying kidney and replenishing lean pulp" method can effectively achieve this goal.

INTRODUCTION

Review question / Objective: The aim of this meta-analysis of randomized controlled trials is to evaluate the efficacy of "tonifying kidney and replenishing lean pulp" method in the treatment of neurological function defects after ischemic stroke. Could the use of the therapy improve NIHSS and ADL in patients with ischemic stroke?

Rationale: There are significant implications for improving the clinical outcomes and quality of life of patients with ischemic stroke. It has been shown that "tonifying kidney and replenishing lean pulp" method can effectively improve the

clinical symptoms and quality of life of patients with ischemic stroke.Therefore, this study conducted a meta-analysis based on the literature to screen clinical studies that applied Bushen prescription to treat ischemic stroke and provide an evidence-based basis for this treatment with a view to guiding clinical diagnosis and treatment.

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METHODS

Search strategy: This systematic review was conducted according to the Cochrane Handbook guidance, using a computer to search the following databases: China National Knowledge Infrastructure, Wanfang database, VIP, Sinomed, PubMed, Cochrane Library and Web of Science. Search terms in Chinese: ①补肾 ②益肾 ③卒中 ④中风 ⑤脑梗塞 ⑥脑梗死. Search terms in English: ① tonify kidney ② nourish kidney ③ Bushen ④ Yishen ⑤ brain infarction ⑥ stroke. Boolean logic was used to connect the search terms, and the search frames were edited separately according to the characteristics of different linguistic application habits and databases, with the following basic logic: Chinese (① or ②) and (③ or ④ or ⑤ or ⑥), English (① or ② or ③ or ④) and (⑤ or ⑥). Both subject headings and free words were searched separately, and literature entries were identified after repeatedly search, which were saved by a dedicated format after obtaining literature entries.

Participant or population: Patients admitted to hospital with a confirmed diagnosis of ischemic stroke, age > 18 years, gender, disease stage, severity, and complications were not restricted.

Intervention: Addition of Bushen herbal formula orally based on treatment regimen in control group.

Comparator: Conventional Western medical treatment.

Study designs to be included: Studies must be clinical randomized controlled trials (RCTs) or quasi RCTs in Chinese or English. The number of included cases is consistent with statistical methods. All literatures are retrieved from the above literature database.

Eligibility criteria: Participant or population: Patients admitted to hospital with a confirmed diagnosis of ischemic stroke, age > 18 years, gender, disease stage, severity, and complications were not restricted. Intervention : Addition of Bushen herbal formula orally based on treatment regimen in control group. Comparator: Conventional Western medical treatment. Main outcome(s) : Clinical overall response rate. Additional outcome(s): National Institute of Health stroke scale (NIHSS) and Activity of Daily Living (ADL).

Information sources: All information is collected in the electronic databases.

Main outcome(s): Clinical overall response rate.

Data management: Two investigators independently and independently retrieved the above databases and collated the data. First, the article abstract information was imported into the MedRef V5.0 software, through which the duplicate articles were excluded by checking the titles and publication time; Then we read the literature title, abstract, exclude animal experiments, review, irrelevant literature, etc., to select RCT type clinical studies; The screened articles were downloaded from scrutinized full texts to select studies whose subjects, intervention and control measures, and outcome measures were in accordance with the guidelines. The

extracted data included: basic information of the literature (title, author, year of publication), methodology (experimental design, sample size, etc.), study subjects (gender, age structure, diagnostic criteria), interventions (basic treatment protocol in control group, dosage and time of administration in experimental group), outcome measures (overall response rate, NIHSS score, ADL score, drop out lost to follow-up, etc.

Quality assessment / Risk of bias analysis: Two investigators independently performed a quality review of the methodology of the included studies using the risk of bias tool provided by the Cochrane Collaboration. Types of bias included: (1) random generation, i.e. bias resulting from unjustified methods of generation of random sequences (2) Allocation concealment, that is, Unblinding of investigators to participants before grouping resulting in bias in the grouping being subjected to the intervention (3) Implementation of blinding, including blinding of investigators and participants, and implementation of a two-part bias for outcome assessment (4) Incomplete data, that is, bias resulting from missing data due to reasons such as loss to follow-up (5) Selective reporting, that is, bias resulting from incomplete reporting of outcome measures or from large differences from those prespecified in the plan book (6) Other sources of bias.

Strategy of data synthesis: Review Manager 5.4 software provided by Cochrane Collaboration was applied for data analyses. For binary variables, odds ratio (OR) and 95% confidence interval (95% CI) were used as the effect analysis statistics; For continuous variables, mean difference (MD) and 95% CI were used as statistics. The heterogeneity test was performed using chi square test, and the heterogeneity size was evaluated by I2.When I2 ≤ 50% and P > 0.1, no significant heterogeneity between studies was considered, a fixed effects model was used for analysis;When I2 ≥ 50% or P ≤ 0.1, suggesting statistical heterogeneity among studies, further clinical heterogeneity or methodological heterogeneity was judged among studies, sensitivity analyses were performed according to their sources if present and random effects models were directly adopted for analysis if absent.Meta analysis results were presented using forest plots, and publication bias was presented using funnel plots.

Subgroup analysis: No subgroup analysis is performed in this article.

Sensitivity analysis: If there was statistical heterogeneity across studies, sensitivity analyses were conducted if present, or analyses were performed by taking a random effects model directly if absent.

Language: The language is limited to Chinese and English.

Country(ies) involved: China.

Keywords: Ischemic stroke; Kidney brain homotherapy; tonifying kidney and replenishing lean pulp; Meta analysis.

Contributions of each author:
Author 1 - Xin Li - The author drafted the manuscript and retrieved, extracted, collated data, and participated in part of subject design work.
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