INPLASY PROTOCOL

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

Conflicts of interest: **None.**

Effects and safety of Buyang-huanwu Decoction for the treatment of patients with acute ischemic stroke: a protocol of systematic review and meta-analysis

Jiang, C[1]; Xu, YC[2]; Zhang, W[3]; Pan, W[4]; Chao, X[5].

Review question / Objective: **Does Buyang-huanwu Decoction (BYHWD) effectively and safety treat acute ischemic stroke (AIS)?**
Condition being studied: **Buyang-huanwu Decoction; acute ischemic stroke.**
Information sources: **We will search Cochrane Library, EMBASE, MEDLINE, CINAHL, PsycINFO, Scopus, Allied and Complementary Medicine Database, VIP Database, and China National Knowledge Infrastructure for related trials published from initial time of each electronic database to March 1, 2020 without any language and publication status limitations. Any randomized controlled trials which focus on assessing the effects and safety of BYHWD alone against any other interventions for the treatment of AIS will be included. The Cochrane Library search strategy is presented. We will adapt similar search strategies to the other electronic databases. In addition to the electronic databases, we will also search other sources, such as websites of clinical trial registry, dissertations, conference proceedings, and reference lists of included trials or related reviews.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 April 2020 and was last updated on 24 April 2020 (registration number INPLASY202040169).

INTRODUCTION

Review question / Objective: **Does Buyang-huanwu Decoction (BYHWD) effectively and safety treat acute ischemic stroke (AIS)?**

Condition being studied: **Buyang-huanwu Decoction; acute ischemic stroke.**

METHODS

Participant or population: **The patients will be adults (18 years old or more) who were diagnosed as AIS. No limitations on country, ethnicity, gender, economic status and educational background will be implemented.**

Intervention: All types of BYHWD for the treatment of patients with AIS will be selected as an experimental intervention. However, patients who received the combination of BYHWD with other managements are not qualified in this study.

Comparator: In the control group, patients could undergo any treatments, but not any forms of BYHWD.

Study designs to be included: Only published or unpublished randomized controlled trials (RCTs) will be included, which explored the effects and safety of BYHWD for AIS.

Eligibility criteria: Only published or unpublished RCTs will be included, which explored the effects and safety of BYHWD for the treatment of patients with AIS.

Information sources: We will search Cochrane Library, EMBASE, MEDLINE, CINAHL, PsycINFO, Scopus, Allied and Complementary Medicine Database, VIP Database, and China National Knowledge Infrastructure for related trials published from initial time of each electronic database to March 1, 2020 without any language and publication status limitations. Any randomized controlled trials which focus on assessing the effects and safety of BYHWD alone against any other interventions for the treatment of AIS will be included. The Cochrane Library search strategy is presented. We will adapt similar search strategies to the other electronic databases. In addition to the electronic databases, we will also search other sources, such as websites of clinical trial registry, dissertations, conference proceedings, and reference lists of included trials or related reviews.

Main outcome(s): Primary outcomes are the proportion of recurrent ischemic stroke, symptomatic intracerebral haemorrhage, and the number of all-cause mortality. Secondary outcomes are functional improvement, as measured by the validated Barthel index or other scales; quality of life, as assessed by the 36-Item Short Form Health Survey; and frequency and severity of adverse events.

Data management: Two investigators will extract the essential data from the included trials, independently and respectively. Any different ideas between both of them will be resolved by consultation with a third investigator. The included data consists of study characteristics and methodology (such as first author, publication date, study setting, study design, randomization, study duration, follow-up duration, withdrawals, etc); participant characteristics (such as age, gender, ethnicity, diagnosis, eligibility criteria, etc); details of interventions and comparators (types of delivery, frequency, duration of delivery, dosage, etc), outcomes (all primary and secondary outcomes, safety, etc), funding information and conflict of interests. If reported data of included trials are insufficient or missing, we will contact original corresponding authors to request them.

Quality assessment / Risk of bias analysis: Two investigators will independently appraise the risk of bias for each included trial using Cochrane risk of bias tool. Any divergences will be solved by a third investigator through consultation. This tool has 7 domains, and each item is evaluated as high, unclear or uncertain risk of bias.

Strategy of data synthesis: In this study, all extracted data will be synthesized and analyzed using RevMan 5.3 software. In addition, we will also perform a systematic review and meta-analysis if the collected data are judged to be similar adequate to make certain a result that is meaningful. We will express continuous values using mean difference or standardized mean difference and 95% confidence intervals (CIs), and dichotomous values utilizing risk ratio and 95% CIs. Statistical heterogeneity across included trials will be checked using I^2 statistics. I^2 ≤50% shows acceptable heterogeneity, and a fixed-effect model is used. If sufficient data on the same outcome measurement are collected, a meta-analysis will be conducted. I^2 >50% presents significant heterogeneity, and a

random-effect model will be employed. Subgroup analysis will be performed to explore the causes of substantial heterogeneity. If the data is deemed not to be pooled, the results will be elaborated as a narrative summary.

Subgroup analysis: Subgroup analysis will be undertaken to search potential causes of heterogeneity in study characteristics, participant characteristics, study methods, intervention and controls, and outcomes.

Sensibility analysis: Sensitivity analysis will be carried out to identify the reliability and stability of aggregation results through eliminating trials with high risk of bias.

Country(ies) involved: China.

Keywords: Buyang-huanwu Decoction; acute ischemic stroke; randomized controlled trial; effects; safety.