INPLASY PROTOCOL

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

Conflicts of interest: None declared.

Gunao-Yizhi Decoction combined with donepezil for vascular dementia: a systematic review and meta-analysis

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Review question / Objective: Gunao-Yizhi Decoction combined with donepezil for vascular dementia: a systematic review and meta-analysis.

Condition being studied: Vascular dementia (VaD) is a serious manifestation of vascular cognitive impairment (VCI), accounting for 12 ~ 20% of all causes of dementia, only inferior to Alzheimer's disease. It can be secondary to stroke and other cerebrovascular diseases. Gunao-Yizhi Decoction has the effects of supplementing intelligence, strengthening marrow, resolving phlegm, and reducing turbidity. It is clinically used for the treatment of vascular dementia. However, there is still a lack of systematic evaluation of its efficacy and safety.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 April 2022 and was last updated on 16 April 2022 (registration number INPLASY202240094).

INTRODUCTION

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intelligence, strengthening marrow, resolving phlegm, and reducing turbidity. It is clinically used for the treatment of vascular dementia. However, there is still a lack of systematic evaluation of its efficacy and safety.

METHODS

Search strategy: We reviewed databases including China National Knowledge Infrastructure (CNKI), Chinese Science and Technology Periodical Database (VIP), Wanfang database (Wanfang Data), China Biology Medicine disc(CBM), PubMed, MEDLINE, and Cochrane library. The search date for the system was built to April 1, 2022. We used keyword combinations to retrieve literature, such as Gunao-Yizhi Decoction OR Gunao-Yizhi OR vascular dementia OR vascular cognitive impairment OR post-stroke dementia OR post-stroke cognitive impairment OR dementia OR VD OR VaD.

Participant or population: Patients who are diagnosed with vascular dementia according to the clinical diagnostic criteria of vascular dementia, Diagnostic efficacy criteria of TCM diseases, or other diagnostic criteria for VaD will be included. There was no specific restriction on age, gender, and race.

Intervention: Gunao-Yizhi decoction compared with donepezil was the main intervention.

Comparator: Donepezil was the main comparartor.

Study designs to be included: Randomized controlled trials(RCTs) will be included.

Eligibility criteria: (1) Randomized controlled trials on VaD were included, including English and Chinese literature. (2) Patients who are diagnosed with vascular dementia according to the clinical diagnostic criteria of vascular dementia, Diagnostic efficacy criteria of TCM diseases, or other diagnostic criteria for VaD. There was no specific restriction on

age, gender, and race. (3) The experimental groups were treated with Gunao-Yizhi decoction combined with donepezil, while the control groups were treated with donepezil alone. (4)The clinical total effective rate, mini-mental status examination (MMSE) score, Hasegawa's dementia scale (HDS) score, the level of serum superoxide dismutase (SOD) and level of malonaldehyde(MDA), adverse reaction were all adopted to estimate therapeutic efficacy and safety of Gunao-Yizhi decoction in the treatment of VaD.

Information sources: The following bibliographic data bases were searched: MEDLINE (from 1948 to Present), EMBASE (from 1948 to April 2022), and The Cochrane Central Register of Controlled Trials (CENTRAL; until April 2022); China National Knowledge Infrastructure(CNKI, from establishment to April 2022), Wanfang database(Wanfang, from establishment to April 2022), Chinese Science and Technology Periodical Database (VIP, from establishment to April 2022), China Biology Medicine disc(CBM, from establishment to April 2022).

Main outcome(s): Clinical efficiency;MMSE score.

Additional outcome(s): HDS score; Serum SOD Level; Serum MDA Level.

Quality assessment / Risk of bias analysis: Two reviewers will independently assess risk of bias based on the following domains from recommendations from the Cochrane handbook: 1. Adequate sequence generation; 2. Allocation concealment; 3. Blinding; 4. Incomplete outcome data and how it was addressed; 5. Selective reporting of the outcome; 6. Any other biases. results of bias assessment will be presented in a figure and a graph indicating low, high or unclear risk of bias for each of the 6 items in each trial. Sensitivity analysis will be conducted based on the bias assessment to assess robustness of results.

Strategy of data synthesis: Risk ratio (RR) for both fixed and random effects models

(weighting by inverse of variance) will be used. A continuity correction will also be used for cells with zero values. According to the Cochrane handbook,the I2 will be considered non-important (60%), Results will be assessed using forest plots and presented as RRs for the main outcome and secondary outcomes. An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies. Publication bias will be assessed by a funnel plot for meta-analysis and quantified by the Egger method. Statistical analysis will be conducted using RevMan 5.3 Software for PC.

Subgroup analysis: We will consider subgroups such as course of treatment, dosage of donepezil, etc.

Sensitivity analysis: We will conduct sensitivity analysis of outcome indicators and exclude references article by article. If the heterogeneity changes after excluding a certain reference, it indicates that the reference may be the source of heterogeneity.

Language: English.

Country(ies) involved: China.

Keywords: Gunao-Yizhi decoction, donepezil, vascular dementia, Meta-analysis.

Contributions of each author:
Author 1 - Yibin Hu - Author 1 contributed to the conceptualization, and drafted the manuscript.
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Author 3 - Xiuju Guan - The author contributede to the development of the formal analysis.
Author 4 - Hanru Hou - The author provided statistical expertise, and the software.
Author 5 - Shuyue Bi - The author contributede to the development of the formal analysis.
Author 6 - Changning Liu - The author contributed to reviewing and editing the manuscript.
Author 7 - Mingxiang Li - The author conteibuted to the methodology.