

INPLASY PROTOCOL

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None declared.

Efficacy and safety of Yangxue Qingnao granules for the treatment of essential hypertension: a protocol for systematic review and meta-analysis

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Review question / Objective: Yangxue Qingnao granules is a kind of Chinese patent medicine that has been used to treat essential hypertension. The objective of this protocol is to systematically evaluate the efficacy and safety of Yangxue Qingnao granules in the treatment of essential hypertension.

Information sources: PubMed, EMBase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, Wanfang Data, China Science and Technology Journal Database, and China Biology Medicine disc will be searched by computer from inception to August 27, 2021, regardless of language. Grey literature, Chinese Clinical Trial Registry, and Clinical Trials will also be searched as supplements.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 September 2021 and was last updated on 05 September 2021 (registration number INPLASY202190015).

INTRODUCTION

Review question / Objective: Yangxue Qingnao granules is a kind of Chinese patent medicine that has been used to treat essential hypertension. The objective of this protocol is to systematically evaluate the efficacy and safety of Yangxue Qingnao

granules in the treatment of essential hypertension.

Condition being studied: Essential hypertension is a cardiovascular syndrome with elevated systemic arterial pressure as the main clinical manifestation, accompanied by symptoms such as headache, vertigo and palpitations, ect. In

2010, about 1.39 billion individuals suffered from hypertension globally, and the figure will be close to 1.5 billion by 2025. Stroke, coronary heart disease, end-stage kidney disease and other serious cardiovascular and cerebrovascular complications caused by hypertension lead to high disability and mortality. Worldwide, it is estimated that 10.4 million people die from hypertension each year. As a result, elevated blood pressure remains a leading cause of death and has become a heavy burden on families and society. Common antihypertensive drugs involve calcium channel blockers (CCB), angiotensin converting enzyme inhibitors (ACEI), angiotensin receptor blockers (ARB), diuretics and β -blockers, as well as fixed ratio compound formulations composed of the above drugs. Despite the remarkable effect of western antihypertensive drugs, there are still some patients with unsatisfactory blood pressure control. Yangxue Qingnao granules (YXQNG) used in the treatment of essential hypertension in China is a kind of Chinese patent medicine with the effect of nourishing blood, calming liver, promoting blood circulation and clearing collaterals. Clinical studies have shown that YXQNG can reduce blood pressure, improve blood pressure variability, improve clinical symptoms such as headache and vertigo, protect target organs, and have fewer adverse reactions. However, there is still a lack of high-quality evidence about the efficacy and safety of YXQNG in the treatment of essential hypertension.

METHODS

Participant or population: Participants with essential hypertension will be included without limitation of age, gender and race.

Intervention: The intervention group was given Yangxue Qingnao granules on the basis of conventional antihypertensive drugs. Conventional antihypertensive drugs include CCB, ACEI, ARB, diuretics, β -blockers and fixed ratio compound formulations composed of the above drugs. Studies with less than two weeks of treatment will be excluded.

Comparator: The control group was given conventional antihypertensive drugs. Basic interventions, if any, should be consistent between the two groups. Studies with less than two weeks of treatment will be excluded.

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

Eligibility criteria: Participants with essential hypertension will be included without limitation of age, gender and race. In accordance with “2020 International Society of Hypertension Global Hypertension Practice Guidelines”, essential hypertension is defined as three measurements of clinic blood pressure on different days with SBP \geq 140mmHg and/or DBP \geq 90mmHg without antihypertensive drugs. Participants with secondary hypertension will be excluded.

Information sources: PubMed, EMBase, Web of Science, Cochrane Library, China National Knowledge Infrastructure, Wanfang Data, China Science and Technology Journal Database, and China Biology Medicine disc will be searched by computer from inception to August 27, 2021, regardless of language. Grey literature, Chinese Clinical Trial Registry, and Clinical Trials will also be searched as supplements.

Main outcome(s): Main outcomes will be systolic blood pressure (SBP) and diastolic blood pressure (DBP).

Additional outcome(s): Additional outcomes will include results measured by 24 hours ambulatory blood pressure monitoring (average 24-h SBP, average 24-h DBP, average daytime SBP, average daytime DBP, average nighttime SBP and average nighttime DBP), the effective rate of lowering blood pressure, symptoms, and adverse events.

Quality assessment / Risk of bias analysis: Two reviewers will independently evaluate the quality of the included studies using the risk-of-bias tool for randomized trials provided by Cochrane Handbook for

Systematic Reviews of Interventions 6.2. The main items include bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in measurement of the outcome and bias in selection of the reported result. Each item is divided into three level: low risk of bias, high risk of bias or some concerns. Any disagreement will be discussed and resolved with a third reviewer.

Strategy of data synthesis: Data synthesis will be performed using RevMan 5.3 software. For dichotomous data, rate ratio and 95% confidence interval will be used as summary measures. For continuous data, mean difference and 95% confidence interval will be calculated. A P value.1 and $I^2 \leq 50\%$, a fixed effect model will be used for meta-analysis. Otherwise, heterogeneity will be considered significant and a random effect model will be used when $P > 50\%$. If meta analysis is not appropriate, we will only perform a descriptive analysis.

Subgroup analysis: If there is significant heterogeneity in included studies, subgroup analysis will be conducted according to age, hypertension grade, dosage of Yangxue Qingnao granules, type of conventional antihypertensive drugs, course of treatment, and traditional Chinese medicine syndrome type.

Sensitivity analysis: To ensure the stability of the synthetical results, sensitivity analysis will be carried out by eliminating individual studies one by one.

Country(ies) involved: China.

Keywords: Yangxue Qingnao granules; essential hypertension; systematic review; meta-analysis; protocol; traditional Chinese medicine.

Contributions of each author:

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