INPLASY PROTOCOL

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Conflicts of interest:
None.

The efficacy and safety of Banxia Baizhu Tianma Decoction with Wendan Decoction for essential hypertension: a systematic review and meta-analysis

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Review question / Objective: **Whether Banxia Baizhu Tianma Decoction with Wendan Decoction could treat essential hypertension? Whether we could evaluate the efficacy and safety of Banxia Baizhu Tianma Decoction with Wendan Decoction for essential hypertension from multi-center?**
Condition being studied: **Hypertension is a complex syndrome, affecting the health of people worldwide. Hypertension can cause damage to cardiovascular, cerebrovascular systems and kidneys. Therefore, it is significant to explore various treatment plan of hypertension. Banxia Baizhu Tianma Decoction and Wendan Decoction are both classic clinical formulations, which have certain curative effects on hypertension. At present, the use of western medicine combined with two prescriptions in clinical treatment of hypertension has a good clinical effect. However, the previous systematic evaluation lacks multi-center evaluation of systolic and diastolic blood pressure and More RCTS have been reported in recent years. Therefore, we will use PICOS principles to systematically evaluate the clinical studies that have been published so far.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 August 2020 and was last updated on 26 August 2020 (registration number INPLASY202080104).

INTRODUCTION

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METHODS

Participant or population: Essential hypertension patients.

Intervention: Banxia Baizhu Tianma decoction and Wendan decoction (monotherapy of with western treatment). There will be no limit to forms of Banxia Baizhu Tianma decoction and Wendan decocotion.

Comparator: Conventional western drugs.

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

Eligibility criteria: RCT of Banxia Baizhu Tianma decoction with Wendan decoction for essential hypertension which is limited to Chinese and English.

Information sources: Databases including Pubmed, Embase, the Cochrane Library, Web of Science, CNKI, WanFang database, VIP and Chinese Biomedical Literature Database will be searched.

Main outcome(s): (1) markedly effective: BP decreased by 10 mmHg and reached the normal range; (2) effective: BP decreased by <10 mmHg but reached the normal range; (3) invalid: did not meet the above criteria. Clinical total effective rate= [(markedly effective+effective)/total number of patients]*100%.

Additional outcome(s): Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP) and adverse reactions, etc.

Quality assessment / Risk of bias analysis: We will assess the risk of bias in the eligible studies through the risk assessment tool for bias in the Cochrane Handbook version 5.1.0. The evaluation is mainly made from seven aspects:random sequence generation(selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome data (attrition bias), incomplete outcome data (attrition bias), selective reporting (reporting bias) and other biases. And we will evaluate the seven aspects according to "low risk", "Not clear" and "High risk". Two researchers will independently complete the quality assessment . If there are any disagreements in the assessment, we will discuss with a third researcher.

Strategy of data synthesis: We will use Review Manager software (version 5.3) to do the statistics. Dichotomous outcome will be expressed by risk ratio(RR), continuous data will be expressed by mean difference (MD), both with 95% confidence interval(CI). P0.1 and I2<50%, there is no statistical heterogeneity, and the fixed-effect model will be used for analysis. If I2 is over 50%, we will consider that there is a significant heterogeneity of the test and use a random-effect model.

Subgroup analysis: We will perform subgroup analysis to measure and deal with the heterogeneity due to the following reasons: (1) different drugs of control groups; (2) different course of treatment;(4) different age and gender; (3) Risks of bias.

Sensibility analysis: We will perform the sensitivity analysis through remove some type of articles and test the I2 again to assess if low quality studies included.

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Country(ies) involved: China.

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