INPLASY PROTOCOL

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

Conflicts of interest:
The authors declare that there are no conflicts of interests.

Comparative Efficacy of Oral Chinese patent medicine for the treatment of Atrial fibrillation: network meta-analysis of randomized controlled trials

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Review question / Objective: **Participants: Adult patients with atrial fibrillation and structural cardiac disease. Interventions: Oral Chinese patent medicine from the Chinese Pharmacopoeia(2020) and Catalogue of Chinese National Basic Drugs(2018). Comparisons: Anticoagulant and antiarrhythmic therapy. Outcomes: The onset of atrial fibrillation and left ventricular ejection fraction are considered as efficacy outcomes. Vascular events, stroke, mortality and hemorrhage events are be considered as safety outcomes. Study Design: Network meta-analysis.**
Condition being studied: **Adult patients with atrial fibrillation and structural cardiac disease, the patients should be taken at least 1 anticoagulant drug and under antiarrhythmic therapy.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 April 2020 and was last updated on 29 April 2020 (registration number INPLASY202040206).

INTRODUCTION

Review question / Objective: **Participants: Adult patients with atrial fibrillation and structural cardiac disease. Interventions: Oral Chinese patent medicine from the Chinese Pharmacopoeia(2020) and Catalogue of Chinese National Basic Drugs(2018). Comparisons: Anticoagulant and antiarrhythmic therapy. Outcomes: The onset of atrial fibrillation and left ventricular ejection fraction are considered as efficacy outcomes. Vascular events, stroke, mortality and hemorrhage events are be considered as safety outcomes. Study Design: Network meta-analysis.**

Condition being studied: Adult patients with atrial fibrillation and structural cardiac disease, the patients should be taken at least 1 anticoagulant drug and under antiarrhythmic therapy.

METHODS

Participant or population: Adult patients with atrial fibrillation and structural cardiac disease.

Intervention: Oral Chinese patent medicine.

Comparator: Anticoagulant and antiarrhythmic therapy.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 1)Randomized clinical trials (RCTs); 2)The age of participants was between 18 and 80 years old; 3) All participants had documented AF or history of AF within the last 2 years; 4) either of the onset of atrial fibrillation and left ventricular ejection fraction should be considered as primary outcome; 5) The corresponding primary and secondary in the study include at least one of vascular events (pulmonary embolism, peripheral arterial occlusion, systemic embolic events, cardiogenic embolism, arterioscerosis obliterans, vasospasm, venous thromboembolism, deep-vein), stroke, mortality, hemorrhage events (cerebral haemorrhage, dubarachnoid haemorrhage, subdural hematoma, intracranial bleeding) and myocardial infarction; 6) The minimum following-up duration in the study was one month; 7) the full-content of the study can be accessed or viewed; 8)data contained in the study can be extracted or estimated in order to conduct network meta-analysis.

Information sources: PubMed, Embase, Cochrane Library, Wanfang data, SinoMed, VIP database and China National Knowledge Internet (CNKI) which are updated on May 15, 2020.

Main outcome(s): Primary outcome(efficacy outcome): The onset of atrial fibrillation: measured by dynamic electrocardiogram (DCG). Left ventricular ejection fraction: measured by ultrasonic cardiogram. Safety outcome: Vascular events, stroke, mortality, hemorrhage events and myocardial infarction.

Quality assessment / Risk of bias analysis: The methodological quality of eligible studies will be assessed by two review authors independently according to the the Cochrane Handbook for Systematic Reviews of Interventions. The following characteristics will be assessed: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), other bias.

Strategy of data synthesis: We initially carried out a conventional pair-wise meta-analysis which pools direct evidence for each treatment comparison. The fixed-effects model is used in pair-wise meta-analysis and the summary statistics of odds ratio (OR) together with the 95% confidence interval (CI) was produced. Then, a NMA was performed for each clinical outcome by using Bayesian framework which is implemented by the Revman 3.2.3 software. A summary statistics of OR and its 95% credible interval (CrI) was produced by synthesizing both direct and indirect evidence for each treatment comparison with respect to each binary outcomes.

Subgroup analysis: There is no need of subgroup analysis in this network meta-analysis.

Sensibility analysis: Publication bias was assessed by using comparison-adjusted funnel plot with respect to each outcome.

Language: English and Chinese.

Country(ies) involved: China.

Other relevant information: This work was part of the program funded under the

National Natural Science Foundation of China, grant number 81974556. And this work was also part of the program on Guideline for Diagnosis and Treatment of Chinese Medicine in Atrial Fibrillation approved by China Association of Chinese Medicine.

Keywords: efficacy, Atrial fibrillation, Chinese patent medicine, safety, network meta-analysis.

Contributions of each author:

Author 1 - Hongzheng Li - The author 1 contributed to the development of the selection criteria, designed the network meta analysis and drafted the manuscript.
Author 2 - Juan Li - The author 2 provided statistical expertise.
Author 3 - Guang Chen - The author 3 contributed to the development of the selection criteria, and the risk of bias assessment strategy.
Author 4 - Hengwen Chen - The author 4 provided statistical expertise.
Author 5 - Jie Wang - The author read, provided feedback and approved the final manuscript.
Author 6 - Jun Li - The author read, provided feedback and approved the final manuscript.
Author 7 - Zhenpeng Zhang - The author contributed to the development of the selection criteria, designed the network meta analysis.