

# INPLASY PROTOCOL

To cite: Liu et al. Effectiveness and safety of Xinyin Tablet in treatment of chronic heart failure: a protocol of systematic review and Meta-analysis of randomized controlled trials. Inplasy protocol 2020100015. doi: 10.37766/inplasy2020.10.0015

Received: 05 October 2020

Published: 05 October 2020

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**Support:** National projects.

**Review Stage at time of this submission:** Piloting of the study selection process.

**Conflicts of interest:**  
The authors declare that they have no competing interests.

## Effectiveness and safety of Xinyin Tablet in treatment of chronic heart failure: a protocol of systematic review and Meta-analysis of randomized controlled trials

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**Review question / Objective:** The patients (over 18 years old) who meet the diagnosis of chronic heart failure irrespective of their sex or ethnicity will be included this study. In the treatment group, patients must be treated with Western conventional treatment combined with Xinyin Tablet, while the controls treated with the same Western conventional treatment as intervention group. The New York Heart Function Classification, 6-min walk distance (6MWD), traditional Chinese medicine (TCM) symptom scores, the scores of quality of life; c.brain natriuretic peptide (BNP), the cardiac color Doppler ultrasonographic indexes such as left ventricular end-systolic volume (LVs), ejection fraction (EF) and fractional shortening (FS) will be measured as outcomes. We will just include RCTs regardless of the blind method and language.

**Condition being studied:** Chronic heart failure. We will just include RCTs regardless of the blind method and language. The nonclinical researches, duplicate publications, literature lacking data that are needed for our study, studies that have no diagnostic criteria or efficacy criteria, and the baseline data are significantly inconsistent will be excluded.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 October 2020 and was last updated on 05 October 2020 (registration number INPLASY2020100015).

### INTRODUCTION

**Review question / Objective:** The patients (over 18 years old) who meet the diagnosis of chronic heart failure irrespective of their

sex or ethnicity will be included this study. In the treatment group, patients must be treated with Western conventional treatment combined with Xinyin Tablet, while the controls treated with the same

Western conventional treatment as intervention group. The New York Heart Function Classification, 6-min walk distance (6MWD), traditional Chinese medicine (TCM) symptom scores, the scores of quality of life; c.brain natriuretic peptide (BNP), the cardiac color Doppler ultrasonographic indexes such as left ventricular end-systolic volume (LVs), ejection fraction (EF) and fractional shortening (FS) will be measured as outcomes. We will just include RCTs regardless of the blind method and language.

**Condition being studied:** Chronic heart failure.

## METHODS

**Participant or population:** The patients (over 18 years old) who meet the diagnosis of chronic heart failure irrespective of their sex or ethnicity will be included this study.

**Intervention:** In the experimental group, Chronic heart failure patients must be treated with Western conventional treatment combined with Xinyin Tablet.

**Comparator:** In the control group, Chronic heart failure patients treated with the same Western conventional treatment as intervention group.

**Study designs to be included:** We will just include RCTs regardless of the blind method and language. The nonclinical researches, duplicate publications, literature lacking data that are needed for our study, studies that have no diagnostic criteria or efficacy criteria, and the baseline data are significantly inconsistent will be excluded. The protocol followed Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols. Papers in English or Chinese published from their inception to September 2020 will be included without any restrictions. The New York Heart Function Classification, traditional Chinese medicine (TCM) symptom scores, the scores of quality of

life, 6-min walk distance (6MWD) and so on were systematically evaluated.

**Eligibility criteria:** We will just include RCTs regardless of the blind method and language. The nonclinical researches, duplicate publications, literature lacking data that are needed for our study, studies that have no diagnostic criteria or efficacy criteria, and the baseline data are significantly inconsistent will be excluded. The patients (over 18 years old) who meet the diagnosis of chronic heart failure irrespective of their sex or ethnicity will be included this study. In the treatment group, Xinyin tablets combined with Western medicine or Xinyin tablets alone, while the controls could be no intervention, placebo, or western medication. New York Heart Function Classification, traditional Chinese medicine (TCM) symptom scores, the scores of quality of life, 6-min walk distance (6MWD), brain natriuretic peptide (BNP) and the cardiac color Doppler ultrasonographic indexes such as left ventricular end-systolic volume (LVs), ejection fraction (EF) and fractional shortening (FS) will be measured as outcomes.

**Information sources:** Eight electronic databases including Cochrane Library, PubMed, Web of Science (WOS), Excerpt Medica Database (Embase), Chinese Biomedical Literature Database (CBM), China National Knowledge Infrastructure (CNKI), China Scientific Journal Database (VIP), and Wanfang Database will be systematically searched for eligible studies from their inception to September 2020. Language is limited with English and Chinese.

**Main outcome(s):** a. New York Heart Function Classification; b. 6-min walk distance (6MWD).

**Additional outcome(s):** a. traditional Chinese medicine (TCM) symptom scores; b. the scores of quality of life; c. brain natriuretic peptide (BNP); d. the cardiac color Doppler ultrasonographic indexes such as left ventricular end-systolic volume

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(LVs), ejection fraction (EF) and fractional shortening (FS).

**Quality assessment / Risk of bias analysis:** The quality of the included RCTs will be assessed independently by 2 investigators (Xiaoming Dong and Jinhua Kang) in terms of sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting, and other bias, according to the guidance of the Cochrane Handbook for Systematic Review of Interventions. Evidence quality will be classified as low risk, high risk, or unclear risk of bias in accordance with the criteria of the risk of bias judgment. Any disagreements will be resolved via discussion with a third researcher (Xianghui Xu).

**Strategy of data synthesis:** Statistical analyses will be performed using Review Manager 5.3 (Nordic Cochran Centre, Copenhagen, Denmark) and Stata 15.0 (Stata Corp, College Station, TX) statistical software. The outcomes were mainly represented by risk ratio with its 95% confidence intervals. A 2-tailed P value <0.05 was considered statistically significant. Cochrane Q-test and I<sup>2</sup> statistics were used to assess heterogeneity between studies; P < 0.05 or I<sup>2</sup> > 50% indicates statistical heterogeneity. A fixed effect model will be used to calculate the outcomes when statistical heterogeneity is absent; otherwise, the random effects model was considered according to the DerSimonian and Laird method.

**Subgroup analysis:** If the data are available and sufficient, subgroup and meta-regression analysis will be conducted to explore the source of heterogeneity with respect to age, gender, region, tumor stage, sample sizes, follow-up period, chemotherapy regimens, and types of involved studies.

**Sensitivity analysis:** Sensitivity analysis was conducted to explore an individual study's influence on the pooled results by deleting 1 single study each time from pooled

analysis. A summary table will report the results of the sensitivity analyses.

**Country(ies) involved:** China, Japan, Korea.

**Keywords:** effectiveness and safety, Xinyin Tablet, chronic heart failure, meta-analysis.

**Contributions of each author:**

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Author 2 - Xi Huang.

Author 3 - Xianghui Xu.

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Author 7 - Wenjie Long.

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