

# INPLASY PROTOCOL

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**Conflicts of interest:**  
None declared.

## Evidence Support for Xinmailong Injection in the Treatment of Heart Failure: An Overview of Systematic Reviews and Meta-Analyses

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**Review question / Objective:** We expect to find higher-level evidence supporting the efficacy of TCM injection-Xinmailong injection in the treatment of heart failure through the methods outlined in the systematic review, and perhaps it can provide complementary alternative therapy for heart failure treatment. **Condition being studied:** Heart Failure. We have been committed to the research of TCM evidence-based medicine. First, we selected the topic, and then conducted a literature search, and found that the selected topic could continue to be studied. We then developed a protocol for writing an overview and registering the selected topics.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 September 2022 and was last updated on 07 September 2022 (registration number INPLASY202290032).

### INTRODUCTION

**Review question / Objective:** We expect to find higher-level evidence supporting the efficacy of TCM injection-Xinmailong injection in the treatment of heart failure through the methods outlined in the systematic review, and perhaps it can provide complementary alternative therapy for heart failure treatment.

**Rationale:** SRs/MAs on Xinmailong injection interventions for heart failure were comprehensively searched in seven databases. Methodological quality, risk of bias, reporting quality, and quality of evidence were assessed using the Assessment of Multiple Systematic Reviews 2 (AMSTAR-2), the Risk of Bias in Systematic (ROBIS) scale, the list of

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Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), as well as the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) system.

**Condition being studied:** Heart Failure. We have been committed to the research of TCM evidence-based medicine. First, we selected the topic, and then conducted a literature search, and found that the selected topic could continue to be studied. We then developed a protocol for writing an overview and registering the selected topics.

## METHODS

**Search strategy:** We searched the following databases up to September 5, 2022: the Cochrane Register of Controlled Trials (CENTRAL), MEDLINE via PubMed and EMBASE. The following Chinese Medical Databases were also being searched: Wanfang, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM) and Chinese Scientific Journals Database (CSJD)/VIP Information.

**Participant or population:** All patients in the selected studies met the internationally recognized diagnostic criteria for heart failure. No etiology, race, severity, or course of disease were used as exclusion criteria.

**Intervention:** The experimental group considered XML injection plus conventional treatment as the treatment strategy.

**Comparator:** The control group could be combined with placebo or other traditional Chinese medicine therapy on the basis of conventional western medicine treatment as a control.

**Study designs to be included:** The included systematic review or meta-analysis must be based on human studies of randomized controlled trials (RCTs), and the language is limited to English and Chinese.

**Eligibility criteria:** Inclusion criteria"(1) The included systematic review or meta-analysis must be based on human studies of randomized controlled trials (RCTs), and the language is limited to English and Chinese.(2) All patients in the selected studies met the internationally recognized diagnostic criteria for heart failure. No etiology, race, severity, or course of disease were used as exclusion criteria. The experimental group considered XML injection plus conventional treatment as the treatment strategy. The control group could be combined with placebo or other traditional Chinese medicine therapy on the basis of conventional western medicine treatment as a control.(3) Outcome indicators: The main outcome indicators include the total effective rate, left ventricular ejection fraction (LVEF), brain natriuretic peptide (BNP), N-terminal pro-brain natriuretic peptide (NT-Pro BNP), left ventricular end-diastolic dimension (LVEDD) and 6-min walking distance (6 MWD), Troponin I (cTnI), serum inflammatory factors, quality of life score, incidence of adverse reactions, etc.

**Information sources:** Literature from public databases: the Cochrane Register of Controlled Trials (CENTRAL), MEDLINE via PubMed and EMBASE. Chinese Medical Databases: Wanfang, China National Knowledge Infrastructure (CNKI), Chinese Biomedical Literature Database (CBM) and Chinese Scientific Journals Database (CSJD)/VIP Information.

**Main outcome(s):** The main outcome indicators include the total effective rate, left ventricular ejection fraction (LVEF), brain natriuretic peptide (BNP), N-terminal pro-brain natriuretic peptide (NT-Pro BNP), left ventricular end-diastolic dimension (LVEDD) and 6-min walking distance (6 MWD), Troponin I (cTnI), serum inflammatory factors, etc.

**Additional outcome(s):** Quality of life score, incidence of adverse reactions.

**Quality assessment / Risk of bias analysis:** The Grading of Recommendations Assessment, Development, and Evaluation

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(GRADE) system was applied to assess the quality of evidence for inclusion in the SRs/MAs outcome indicators. Evidence quality may be downgraded due to the following 5 criteria: Risk of bias, inconsistency, indirectness, imprecision, and publication bias. The quality of evidence was categorized as high, moderate, low, and very low.

**Strategy of data synthesis:** The literature screening and information extraction were performed independently by two researchers. Endnote X9 was used to filter the relevant articles and remove duplicates. Then the titles and abstracts of the documents were reviewed to search for the documents that may meet the conditions, and the full text was read. Finally, the following information was extracted from each eligible SR/MA by means of standardized tables: First author, country, year of publication, quality assessment tools included in RCTs, treatment measures for treatment groups and control groups, and main conclusion.

**Subgroup analysis:** This study did not involve subgroup analysis.

**Sensitivity analysis:** This study did not involve sensitivity analysis.

**Language restriction:** English and Chinese.

**Country(ies) involved:** China.

**Keywords:** Xinmailong injection; Complementary therapy; Heart Failure; Methodological Quality; Reporting Quality; Quality of Evidence; 9 AMSTAR-2; PRISMA 2020; GRADE.

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