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Combined treatment of heart failure after coronary heart disease

Submission date	Recruitment status	[ ] Prospectively registered
15/05/2025	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/05/2025	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/05/2025	Circulatory System	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Qili cardiotonic capsule and Sacubitril/valsartan are commonly used drugs for the treatment of heart failure. The single drug treatment effect and prognosis are poor, and the combination of traditional Chinese and Western medicine can play the role of treating both symptoms and root causes. However, there are few studies on the combined treatment of heart failure at home and abroad. Therefore, this study took patients with heart failure after coronary heart disease as the research object, and explored the therapeutic effect of Qili cardiotonic capsule combined with Sacubitril/valsartan and its effect on NT-proBNP level.

Who can participate?
Patients with coronary heart disease and heart failure. The results showed that there were 33 males and 20 females in the experimental group, with an average age of 68.89 ± 10.60 years. There were 27 males and 23 females in the control group, with an average age of 68.30 ± 11.44 years.

What does the study involve?
The control group was treated with Sacubitril/valsartan orally, and the experimental group was treated with Sacubitril/valsartan combined with Qili cardiotonic capsule.

What are the possible benefits and risks of participating?
The combination of Sacubitril/valsartan and Qili cardiotonic capsule was more effective in the treatment of patients with coronary heart disease complicated with heart failureit can improve cardiac function in a short period of time.

Where is the study run from?
This study was conducted at Tianshui Hospital of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
This study was starting on October 1, 2022 and ending on April 1, 2025.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Lan Hai , hanlan_lher@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Clinical effect observation of Sacubitril/valsartan combined with Qili cardiotonic capsule on patients with heart failure after coronary heart disease

Acronym
CEOSVQLC

Study objectives
The combination of Sacubitril/valsartan and Qili cardiotonic capsule was more effective in the treatment of patients with coronary heart disease complicated with heart failure, and can improve cardiac function in the short term.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 10/04/2025, the Ethics Committee of Tianshui Traditional Chinese Medicine Hospital (Near the intersection of Nanming Road and Jiehe North Road in Zhongcheng Street, Tianshui City, 741000, China; +86-09388212475; mayupeng@21cn.com), ref: TSSZY2025-LY004-04

Primary study design
Interventional

Study design
Single center randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Combined treatment of heart failure after coronary heart disease

Interventions
106 patients with coronary heart disease and heart failure were randomly divided into control group and experimental group by simple random grouping method, 53 cases in each group.The control group was treated with Sacubitril/valsartan orally, and the experimental group was treated with Sacubitril/valsartan combined with Qili cardiotonic capsule. Both groups were followed up for 6 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sacubitril/valsartan, Qili cardiotonic capsule

Primary outcome(s)
1. N-terminal pro-brain natriuretic peptide (NT-proBNP) is measured using immunoassay at baseline and at 6 months
2. 6-minute walking distance is measured using the 6-minute walking test (6MWT) at baseline and at 6 months
3. Left ventricular ejection fraction (LVEF) is measured using echocardiography at baseline and at 6 months
4. Left ventricular end-systolic diameter (LVESD) is measured using echocardiography at baseline and at 6 months
5. Left ventricular end-diastolic diameter (LVEDD) is measured using echocardiography at baseline and at 6 months

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Meeting the 2021 European Society of Cardiology diagnostic criteria and treatment guidelines for acute and chronic heart failure;

2. The heart failure classification conformed to the New York Heart Association (NYHA) cardiac function classification II-IV;
3. Chronic heart failure with coronary heart disease.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
55 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
106

Key exclusion criteria
1. Combined with other cardiovascular diseases leading to heart failure, such as severe valvular disease, malignant arrhythmia, acute myocarditis, acute myocardial infarction, various types of cardiomyopathy, malignant hypertension
2. Complicated with severe liver, kidney, lung or other important organ dysfunction
3. Combined with malignant tumor; severe anemia requiring blood transfusion
4. Patients who could not complete all follow-ups
5. Patients who did not test blood routine within 24 hours of hospitalization

Date of first enrolment
01/12/2022

Date of final enrolment
31/08/2024

Locations

Countries of recruitment
China

Study participating centre
Tianshui Hospital of Traditional Chinese Medicine
Near the intersection of Nanming Road and Jiehe North Road in Zhongcheng Street
Tianshui City

China
741000

Sponsor information

Organisation
Tianshui Hospital of Traditional Chinese Medicine

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
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IPD sharing plan summary
Available on request