

Combined treatment of heart failure after coronary heart disease

Submission date 15/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/05/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/05/2025	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Qili cardiotoxic 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 cardiotoxic 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 cardiotoxic capsule.

What are the possible benefits and risks of participating?

The combination of Sacubitril/valsartan and Qili cardiotoxic capsule was more effective in the treatment of patients with coronary heart disease complicated with heart failure. It 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

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

Acronym

CEOSVQLC

Study objectives

The combination of Sacubitril/valsartan and Qili cardiotoxic 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

Study design

Single center randomized controlled trial

Primary study design

Interventional

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 cardiotoxic capsule. Both groups were followed up for 6 months.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Sacubitril/valsartan, Qili cardiotoxic 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