

# Combined treatment of heart failure after coronary heart disease

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<b>Registration date</b> 20/05/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/05/2025	<b>Condition category</b> 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  $68.89 \pm 10.60$  years. There were 27 males and 23 females in the control group, with an average age of  $68.30 \pm 11.44$  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

### 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 cardiogenic capsule. Both groups were followed up for 6 months.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Sacubitril/valsartan, Qili cardiogenic 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