

Qishen Yiqi Dripping Pills improve cardiopulmonary function in post-percutaneous coronary intervention patients

Submission date 26/09/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/09/2024	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

The study will aim to investigate the effects of Qi Shenyi Qi Drops/Pills on cardiopulmonary function, traditional Chinese medicine symptom scores, and quality of life in patients with coronary heart disease (CHD) who have undergone percutaneous coronary intervention (PCI). It will seek to introduce new perspectives for integrating traditional Chinese and Western medicine.

Who can participate?

Patients aged 25-80 years old with CHD who have undergone PCI

What does the study involve?

Participants will be randomly assigned to receive either Qi Shenyi Qi Drops/Pills or a placebo. The study will use double-blind, placebo-controlled methods to ensure unbiased results. Cardiopulmonary exercise testing (CPET) will be used to evaluate the impact of the treatment on cardiopulmonary function and traditional Chinese medicine symptoms.

What are the possible benefits and risks of participating?

Participants may benefit from improved cardiopulmonary function and symptom relief. However, as with any clinical study, there may be risks, including potential side effects from the medication.

Where is the study run from?

Yijishan Hospital Affiliated with Wannan Medical College

When is the study starting and how long is it expected to run for?

April 2023 to June 2025

Who is funding the study?

China Traditional Chinese Medicine Research and Innovation Fund

Who is the main contact?
Prof Deguo Wang, wangdeguo@wnmc.edu.cn

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Prof Deguo Wang

ORCID ID

<https://orcid.org/0000-0002-9489-7300>

Contact details

The First Affiliated Hospital of Wannan Medical College, Yijishan Hospital, Zheshan Western Road No. 2
Wuhu City, Anhui Province
China
241001
+8618226726360
wangdeguo@wnmc.edu.cn

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CCA-TCM-002

Study information

Scientific Title

Evaluation of the effect of Qishen Yiqi Dripping Pills on cardiopulmonary exercise tests in patients with coronary heart disease after percutaneous coronary intervention

Study objectives

The improvement of Qishen Yiqi Dripping Pills in traditional Chinese medicine (TCM) syndrome and cardiovascular protection observed in patients with coronary heart disease (CHD) after undergoing interventional surgery, which incorporates TCM, is attributed to its positive effects on enhancing the patient's cardiopulmonary function. Cardiopulmonary exercise testing (CPET) can serve as a pivotal, objective metric for the clinical assessment of the efficacy of TCM treatments.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 18/09/2023, Scientific Research and New Technology of Wannan Medical College Yijishan Hospital IRB (Zheshan Western Road No 2, Wuhu City, Anhui Province, 241001, China; +86 553 573 9209; wupei@yjsy.com), ref: (2023) Ethics Approval No. (106)

Study design

Randomized double-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Quality of life, Treatment, Efficacy

Health condition(s) or problem(s) studied

Cardiovascular protection observed in post-PCI patients with coronary heart disease (CHD)

Interventions

This is a randomized, double-blind, placebo-controlled study of the effects of Qishen Yiqi Dripping Pills on cardiopulmonary function, Chinese medicine symptom scale, and quality of life in patients with coronary heart disease (CHD) after PCI.

Control group: Patients in post-PCI receive "QishenYiqi dripping pill Placebo"(0.5 PO. TID) plus general drug treatment including lipid-lowering drugs (aspirin 100 mg qd, Tigelor 90 mg bid), antiplatelet drugs (Atorvastatin 20 mg QN/Ezemeb 10 mg QD).

Intervention group: Patients in post-PCI receive "QishenYiqi dripping pill"(0.5 PO. TID) plus general drug treatment including lipid-lowering drugs(aspirin 100 mg qd, Tigelor 90 mg bid), antiplatelet drugs (Atorvastatin 20 mg QN/Ezemeb 10 mg QD).

Drug name: QishenYiqi dripping pill

Dosage and method: 0.5g/PO.

Frequency of administration: three times a day.

Total duration of treatment: three months

Follow-up for all treatment arms: three months

Randomisation process(double-blind): Random number table

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Qishen Yiqi Dripping Pills

Primary outcome(s)

Cardiopulmonary function is measured using Cardiopulmonary Exercise Testing at 3 months after PCI

Key secondary outcome(s)

1. Quality of life is measured using the 36-Item Short Form Survey Instrument (SF-36) at baseline, 1, 2 and 3 months after PCI
2. Cardiac function is measured using echocardiography at baseline and 3 months after PCI
3. Serum inflammatory markers (CRP, IL-6, TNFa, etc.) are measured using chemiluminescence at 3 months after PCI
4. Qi deficiency and blood stasis syndrome scores are measured by a Traditional Chinese medicine doctor using Traditional Chinese four ways of diagnosis including looking, listening, questioning and feeling the pulse 3 months after PCI.

Completion date

30/06/2025

Eligibility

Key inclusion criteria

1. Aged 25-80 years old
2. Patients with acute coronary syndrome after coronary interventional treatment
3. Traditional Chinese medicine Qi deficiency and blood stasis certificate (both certificates include: phlegm certificate, Yin deficiency, Yang deficiency certificate)
4. Co Cardiopulmonary exercise testing (CPET) contraindications

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

25 years

Upper age limit

80 years

Sex

All

Key exclusion criteria

1. Serious heart complications such as ventricular septal perforation
2. Cardiogenic shock and cardiac arrest
3. Vascular interventional treatment success but with vascular lesions with greater than 70% occlusion
4. Severe liver and kidney dysfunction, mental abnormalities, hematopoietic dysfunction, co-infection or severe immune system diseases
5. Pregnant or lactating women

Date of first enrolment

01/01/2024

Date of final enrolment

30/04/2025

Locations

Countries of recruitment

China

Study participating centre

Yijishan Hospital Affiliated to Wannan Medical College

Zheshan Western Road No 2

Wuhu City, Anhui Province

China

241001

Sponsor information

Organisation

Chinese Cardiovascular Association TCM Fund

Funder(s)

Funder type

Research organisation

Funder Name

China Traditional Chinese Medicine Research and Innovation Fund

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof Deguo Wang, wangdeguo@wnmc.edu.cn

IPD sharing plan summary

Available on request