ISRCTN83433606 https://doi.org/10.1186/ISRCTN83433606

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

Submission date 26/09/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2024	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/09/2024	**Condition category** Circulatory System	[_] Individual participant data [_] 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

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@yjsyy.com), ref: (2023) Ethics Approval No. (106)

Primary study design
Interventional

Study design
Randomized double-blind placebo-controlled study

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, Tigrelor 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, Tigrelor 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