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What is the effect of Xinkeshu tablets added to usual treatment on the function of the circulatory system in patients with coronary artery disease and high blood pressure?

Submission date
03/12/2019

Recruitment status
No longer recruiting

Registration date
05/02/2020

Overall study status
Completed

Last Edited
28/03/2023

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Hypertension (high blood pressure) and coronary artery disease (CAD) are increasingly common. Having these conditions means a person is more likely to suffer a heart attack or stroke. In addition, 3 in 10 patients with CAD suffer from depression. Hypertension and CAD are linked to damage to blood vessels and the blood vessels then start to lose the ability to function normally. Xinkeshu, a traditional Chinese medicine containing herbs, has been proven to reduce blood pressure, improve CAD symptoms and improve depression and anxiety. This study aims to investigate whether Xinkeshu can protect blood vessels in patients with CAD and hypertension, and also whether it can improve symptoms of depression and anxiety.

Who can participate?
Patients aged 18-65 years with CAD and hypertension

What does the study involve?
Participants will be randomly allocated to one of two groups. One group will receive usual treatment for hypertension and CAD (aspirin, atorvastatin and amlodipine). The other group will receive the usual treatment and Xinkeshu tablets. Both groups will take the treatment for 12 weeks. They will have blood samples taken, will have their blood vessels examined using a blood pressure measuring device and ultrasound, and will fill in questionnaires about symptoms of depression and anxiety before they start the treatment and at 4 week s and 12 weeks after the start of treatment.

What are the possible benefits and risks of participating?
Participants will get XKS pills for free to treat their CAD and hypertension. The usual treatment medicines are commonly used and generally safe.

Where is the study run from?
The First Affiliated Hospital, Sun Yat-Sen University (China)

When is the study starting and how long is it expected to run for?
July 2017 to September 2020

Who is funding the study?
Shandong Wohua Pharmaceutical Technology Co Ltd (China)

Who is the main contact?
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Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2017154

Study information

Scientific Title
The protective effect of Xinkeshu tablets on vascular function in patients with coronary artery disease combined with hypertension: a randomized controlled study.

Acronym
X-CHRCS

Study objectives
Xinkeshu tablets have a protective effect on vascular endothelium by improving endothelial progenitor cells function and accelerating vascular repair in patients with coronary artery disease combine with hypertension through the CXCR4/JAK2 signaling pathway.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/08/2017, Ethics Committee of Clinical Research and Experimental Animals, The First Affiliated Hospital, Sun Yat-Sen University in Guangzhou (58 Zhongshan Road 2, Guangzhou, Guangdong, 510000, China; +86 020-87755766; linf7@mail.sysu.edu.cn), ref: 2017 [154]

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available.

Health condition(s) or problem(s) studied
Coronary heart disease combined with hypertension and vascular dysfunction

Interventions
We will recruit 68 patients with hypertension and coronary artery disease who had been admitted to The First Affiliated Hospital, Sun Yat-Sen University. Patients will be randomly divided into XKS group (34) and control group (34). The XKS group will receive routine treatment (aspirin 100 mg qd, atorvastatin 20 mg qd, amlodipine 5 mg qd) combined with Xinkeshu tablets (Shandong Wohua Pharmaceutical Co Ltd), 4 tablets, three times a day for 3 months. The control group will receive routine treatment for 3 months. At the first day, the end of 1st, 2nd and 3rd month, blood samples will be collected, their arterial function will be assessed, and any anxiety and depressive symptoms will be evaluated. The blood sample tests include endothelial microparticles (EMPs), endothelial progenitor cells (EPCs), liver function, kidney function, blood lipid, blood glucose and so on. Arterial function examination includes artery flow-mediated dilation (FMD) and brachial-ankle pulse wave velocity (baPWV). Anxiety and depressive symptoms would be evaluated by using GAD-7 and PHQ-9 score.The patients need to provide their peripheral blood to get their endothelial progenitor cells.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Xinkeshu tablets

Primary outcome measure
1. Brachial arterial flow-mediated dilation measured using ultrasound at baseline, 4 weeks and 12 weeks
2. Brachial-ankle pulse wave velocity measured using a blood pressure measuring device at baseline, 4 weeks and 12 weeks
3. Anxiety assessed using the GAD-7 questionnaire at baseline, 4 weeks and 12 weeks
4. Depression assessed using the PHQ-9 questionnaire at baseline, 4 weeks and 12 weeks

Secondary outcome measures
1. Endothelial microparticles measured using flow cytometry of peripheral blood samples taken at baseline, 4 weeks and 12 weeks
2. Quantity of endothelial progenitor cells measured using flow cytometry of peripheral blood samples taken at baseline, 4 weeks and 12 weeks
3. Blood pressure measured using a tronic sphygmomanometer (HEM-7071, OMRON, China) at baseline, 4 weeks and 12 weeks

Overall study start date
01/07/2017

Completion date

01/09/2020

Eligibility

Key inclusion criteria
1. Aged 18-70 years
2. Diagnosed with hypertension and coronary artery disease and have received regular coronary heart disease secondary prevention drugs and antihypertensive drugs
3. Baseline GAD-7 and PHQ-9 score were both between 5-14 points
4. Have given written informed consent prior to study participation

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Severe liver or kidney dysfunction or malignant tumors
2. Allergic to any component of Xinkeshu tablet
3. Cardiovascular or cerebrovascular accident within previous 3 months
4. Pregnant or lactating women

Date of first enrolment
01/12/2019

Date of final enrolment
30/06/2020

Locations

Countries of recruitment
China

Study participating centre

First Affiliated Hospital, Sun Yat-sen University
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Sponsor information

Organisation
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Shandong Wohua Pharmaceutical Co Ltd

Results and Publications

Publication and dissemination plan
We intend to publish in one of the SCI journals in 2020 after finishing the study.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/07/2021	28/03/2023	Yes	No