

This study investigates how using a combination of Ginkgo leaf extract, Dipyridamole injection, and antiplatelet therapy affects patients suffering from ST-segment elevation myocardial infarction (STEMI) after undergoing percutaneous coronary intervention (PCI)

Submission date 01/04/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/04/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/04/2024	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 difficulties encountered in treating patients with acute ST-segment elevation myocardial infarction (STEMI) following percutaneous coronary intervention (PCI) remain a challenge. Ginkgo biloba injection is frequently administered to alleviate symptoms of angina pectoris and coronary heart disease. The aim of this research was to assess the healing impact of combining ginkgo damo injection with antiplatelet therapy in STEMI patients post-PCI.

Who can participate?

Patients undergoing PCI after acute ST elevation myocardial infarction.

What does the study involve?

Effect of ginkgo damo injection combined with antiplatelet therapy on STEMI patients after PCI.

What are the possible benefits and risks of participating?

The benefits of participating:(1) Access to new treatment opportunities. (2) Reduce the economic burden. (3) You can learn more about the latest information about your disease. (4) Get more attention from doctors. (5) Access to quality medical services.

The risks of participating :it need to expend more energy; the treatment is not effective

Where is the study run from?

The Affiliated Hospital of Weifang Medical University (China)

When is the study starting and how long is it expected to run for?
September 2020 to December 2022

Who is funding the study?
The Affiliated Hospital of Weifang Medical University (China)

Who is the main contact?
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Contact information

Type(s)

Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

20240401

Study information

Scientific Title

Effect of ginkgo damo injection in combination with antiplatelet therapy on the treatment of STEMI patients after PCI

Study objectives

Ginkgo damo injection combined with antiplatelet therapy has a significant effect on STEMI patients after PCI

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 20/06/2023, Medical Ethics Committee of Affiliated Hospital of Weifang Medical College (YNMT) (No. 2428 Yuhe Road, Kuiwen District, Weifang, 261000, China; +86 536 308 1125; wyfyywlcsy@163.com), ref: wyfy-2023-ky-141

Study design

Interventional randomized parallel trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Percutaneous coronary intervention (PCI) in ST-segment elevation myocardial infarction (STEMI)

Interventions

A total of 220 patients who underwent PCI following acute ST-segment elevation myocardial infarction at the Affiliated Hospital of Weifang Medical University were included in this study. Patients were randomly assigned into two groups: the control group (n=100) and the observation group (n=120).

In the control group, patients received standard antiplatelet therapy following PCI, including orally administered aspirin enteric-coated tablets (100mg per dose, once daily) and clopidogrel bisulfate tablets (75mg per dose, once daily) for a continuous treatment duration of 14 days, in addition to basic treatment.

In contrast, the observation group received the same antiplatelet therapy regimen as the control group. Additionally, they were administered ginkgo damo injection. Ginkgo damo injection, consisting of 10mL, was added to 250mL of normal saline and administered via intravenous infusion once daily for a continuous treatment duration of 14 days.

The control group received no additional special treatment beyond the conventional therapy.

Intervention Type

Mixed

Primary outcome measure

Cardiac function index: For the examination of cardiac function index, the cardiac output (CO) and cardiac index (cardiac index) were measured by color Doppler ultrasound (Minrui DC-N2S) before and after treatment in the two groups. CI, left ventricular ejection fraction (LVEF) and other cardiac function indicators.

Secondary outcome measures

1. Bleeding risk: According to Bleeding Academic Research Consortium (BARC) bleeding classification criteria ,the number of cases of type 3 or type 5 bleeding during hospitalization and 30 days after discharge will be counted.
2. Embolization risk: thrombolysis in myocardial infarction (TIMI) blood flow rating and TIMI myocardial perfusion grade (TMPG) :TIMI blood flow grading and myocardial perfusion grading (TMPG) will be compared between the two groups before and after treatment.
3. Major adverse cardiac events (MACE) :Patients will follow up 30 days after hospitalization and discharge and MACE will be recorded, including cardiac death, myocardial infarction, recurrent angina pectoris, and revascularization.

Overall study start date

01/09/2020

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. It meets the diagnostic criteria of acute ST-segment elevation myocardial infarction in the Guidelines for Diagnosis and Treatment of acute ST-Segment Pickup Myocardial Infarction
2. The patient underwent emergency PCI treatment within 12 hours of onset;
3. Age ≥ 17 years old;
4. Complete clinical data.
5. The knowledge and consent of all participants in the study.

Participant type(s)

Patient

Age group

Adult

Lower age limit

51 Years

Upper age limit

81 Years

Sex

Both

Target number of participants

220

Total final enrolment

220

Key exclusion criteria

1. severe congenital heart disease;
2. Patients with severe liver and kidney dysfunction and malignant tumors;
3. Major surgery or trauma, cerebrovascular disease within 6 months;
4. People with cognitive or mental disorders.

Date of first enrolment

01/03/2021

Date of final enrolment

31/10/2022

Locations**Countries of recruitment**

China

Study participating centre**The Affiliated Hospital of Weifang Medical University**

No. 2428 Yuhe Road, Kuiwen District, Weifang City, Shandong Province

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Sponsor information**Organisation**

The Affiliated Hospital of Weifang Medical University

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

The Affiliated Hospital of Weifang Medical University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/06/2024

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