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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 07/04/2024	**Overall study status** Completed	
Last Edited 03/04/2024	**Condition category** Circulatory System	

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

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional randomized parallel trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
51 Years

Upper age limit
81 Years

Sex
All

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
Weifang
China
261000

Sponsor information

Organisation
The Affiliated Hospital of Weifang Medical University

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Affiliated Hospital of Weifang Medical University

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
ly20141006@163.com

IPD sharing plan summary
Available on request