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The effectiveness and safety of a drug-releasing balloon in active cancer patients presenting with ST-segment elevation myocardial infarction (heart attack)

Submission date
23/09/2022

Recruitment status
No longer recruiting

Registration date
27/09/2022

Overall study status
Ongoing

Last Edited
26/09/2022

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and aims
A primary percutaneous coronary intervention (PCI) is a procedure to open the heart artery which has blocked. A drug-eluting stent (DES) is coated with a slow-release medication to help prevent blood clots from forming in a stent. PCI with a DES is the guideline-recommended revascularization strategy in patients presenting with ST-elevation myocardial infarction (STEMI; the most serious type of heart attack). However, there are limited data on the best PCI treatment among patients with active cancer presenting with STEMI. The aim of this study is to compare the efficiency and safety of a drug-eluting balloon (DEB) versus DES during primary PCI for active cancer patients presenting with STEMI.

Who can participate?
Patients with active cancer and presenting with STEMI within 12 hours of symptom onset

What does the study involve?
Participants are randomly allocated to either DEB or DES treatment. The primary endpoint is major bleeding events at 1 year.

What are the possible benefits and risks of participating?
It is expected that the participants receiving DEB treatment could have a signifcantly decreased risk of major bleeding events and might have a lower death rate during the clinical follow-up. Participants may suffer from complications of acute myocardial infarction such as malignant arrhythmia, ventricular septal rupture and cardiac rupture.

Where is the study run from?
Beijing Chaoyang Hospital, Capital Medical University (China)

When is the study starting and how long is it expected to run for?
September 2022 to January 2027

Who is funding the study?
1. Clinical Incubation Program of Beijing Chaoyang Hospital (China)
2. Beijing Municipal Administration of Hospitals (China)

Who is the main contact?
1. Prof. Le-Feng Wang, tatumyong@163.com
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

Comparisons of a drug-eluting balloon versus drug-eluting stent for the treatment of active cancer patients presenting with ST-segment elevation myocardial infarction: a randomized clinical trial

Acronym
DEB-ACST

Study objectives
It is hypothesised that a drug-eluting balloon (DEB) is superior to a drug-eluting stent (DES) in the treatment of active cancer patients presenting with ST-segment elevation myocardial infarction (STEMI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Ethics Committee of Beijing Chaoyang Hospital (No.8, Gongti South Road, Chaoyang District, Beijing, China; +86 (0)10 85231484; cyylunli2019@163.com)

Study design
Prospective single-center open-label superiority randomized trial with blinded evaluation of outcomes

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Optimal management of active cancer patients presenting with STEMI

Interventions
Eligible patients are randomly assigned at a 1:1 ratio to either DEB or DES according to a computergenerated randomization schedule, which is performed by an independent authorized researcher, who is not directly involved in the research project. The details about the procedure of random allocation are blinded to all researchers. Due to the procedure itself, the interventional physicians could not be blinded to the treatment allocation, but patients and researchers who collect and analyze the data are blinded to the treatment allocation.

The PCI procedure will be performed according to current international guidelines and local practice.

In the DEB group, optimal lesion preparation by pre-dilation is required to achieve the goal of a stenosis <30% of vessel diameter, without flowlimiting dissection (grade C–F) and with thrombolysis in myocardial infarction (TIMI) flow grade 3. Subsequently, the DEB is inflated at nominal pressure (8–10 atm) for a minimum of 30 seconds. The ratio of the DEB diameter to the nominal diameter of the vessel is recommended to be between 0.8 and 1.0 to minimize the probability of coronary dissection. And the DEB length is recommended to be at least 5 mm longer than the pre-dilatation balloon to avoid geographical mismatch. A bailout stenting may be recommended if a flow-limiting dissection or a residual stenosis >30% after DEB implantation occurred. Patients with a flow-limiting dissection or a residual stenosis >30% after pre-dilation should be converted to the DES group and enter a prospective registry with the same follow-up procedures as in the randomized trial.

In the DES group, a new-generation DES will be implanted using standard techniques after accomplishing adequate lesion preparation. Post-dilation with noncompliant balloons at high pressure (12–18 atm) is recommended in this group, but the final strategy is left to the operator' s discretion based on the conditions set by the individual study sites.

A successful PCI treatment is defined as a diameter stenosis (DS) <30% and TIMI flow grade 2 in the DEB group and a DS <20% and TIMI flow grade 2 in the DES group by visual assessment.

Intervention Type
Procedure/Surgery

Primary outcome measure
Major bleeding events measured using hospital records and telephone interviews at 6 months and 1 year

Secondary outcome measures
1. Thrombolysis in Myocardial Infarction (TIMI) grade measured using coronary angiography immediately post PCI
2. Resolution of ST-segment elevation (STR) measured using electrocardiogram at 60 min after PCI
3. Cardiac biomarkers level measured using enzyme-linked immunosorbent assay at 24 h, 48 h, and 72 h post PCI
4. Left ventricular ejection fraction (LVEF) measured using echocardiography within 3 days after PCI
5. Cardiac complications measured using hospital records during hospitalization
6. Major adverse cardiac event (MACE) measured using hospital records as well as by telephone interviews during 1-year clinical follow-up

Overall study start date
01/09/2022

Completion date
01/01/2027

Eligibility

Key inclusion criteria

1. Age between 18 and 80 years
2. First STEMI attack
3. Presenting within 12 h of symptom onset
4. Active cancer

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
164

Key exclusion criteria
1. Previous myocardial infarction
2. Non-ST-segment elevation myocardial infarction and unstable angina pectoris
3. Unconsciousness or cardiogenic shock
4. Symptom onset >12 h
5. Mechanical complications
6. Historical cancer

Date of first enrolment
01/01/2023

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
China

Study participating centre
Beijing Chaoyang Hospital, Capital Medical University
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Organisation
Scientific Research Department of Beijing Chaoyang Hospital

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Municipal Administration of Hospitals

Alternative Name(s)
, Beijing Hospital Authority, Beijing Municipal. Administration of Hospitals'

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Funder Name

Investigator initiated and funded

Funder Name
Clinical Incubation Program of Beijing Chaoyang Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/01/2028

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to the principle of informed consent which indicated that the patient's personal data will not be public.

IPD sharing plan summary
Not expected to be made available