ISRCTN14411820 https://doi.org/10.1186/ISRCTN14411820

Long-term outcomes of early stent thrombosis after implanting new-generation drug-eluting stents

Submission date
04/11/2022

Recruitment status
Recruiting

Registration date
09/11/2022

Overall study status
Ongoing

Last Edited
09/11/2022

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 study aims

A stent is a short, wire mesh tube that is inserted into a heart blood vessel where it acts like a scaffold to help keep the vessel open. Although the risk of stent thrombosis (ST; a blood clot that can block the vessel) has become lower in contemporary settings due to improvements in stent design, deployment techniques, adjunctive therapies (other treatments used at the same time to assist the primary treatment) and the use of more potent antiplatelet drugs, it remains a fatal complication with high rates of mortality and disability in patients undergoing percutaneous coronary intervention (PCI; procedures used to open clogged heart vessels). According to the timing of event occurrence, ST can be stratified into early ST (EST), occurring within 30 days after stent implantation, late ST (LST), occurring from 30 days to 1 year after stent implantation, and very late ST (VLST), occurring more than 1 year after stent implantation. Studies suggest the underlying mechanisms are different between EST, LST and VLST. Stent underexpansion and acute malapposition (the lack of contact between the stent and the underlying surface of the vessel wall) have been identified as the most prevalent abnormalities in EST, whereas late malapposition, delayed endothelialization (after stenting, tissue should grow over the stent to form a new lining for the artery wall), uncovered stent struts and new formed/neoatherosclerosis have been regarded as the most important mechanisms for LST and VLST. These heterogeneous causes of ST may lead to different presentations and outcomes for EST, LST and VLST.

Our previous meta-analysis, including 23 studies with a total of 17,592 patients, showed that patients with EST presented more frequently with ST-segment elevation myocardial infarction (STEMI), the most serious type of heart attack, and cardiogenic shock compared with those with LST and VLST. Patients with EST had worse clinical outcomes than patients with LST and VLST in both short-term and long-term follow-up after PCI treatment, which highlights a great need for studies to investigate the optimal strategies for the treatment of patients with EST. Therefore, we aim to perform a multicenter observational study that includes consecutive patients who presented with EST after the implantation of a new-generation drug-eluting stent (DES) to investigate the incidence of major adverse cardiac events after treatment for EST and identify determinants that are associated with these events in a contemporary setting.

Who can participate?
Adults who suffered from definite EST after PCI with new-generation DES

What does the study involve?
The present study will use 10 hospital admissions and follow-up data to identify the long-term prognosis of those individuals who developed an EST after DES implantation.

What are the possible benefits and risks of participating?
Patients will benefit from participation in the study as they will clearly know their physical health condition. Because all data except for follow-up data are retrospectively collected, there are no potential risks of participating.

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?
January 2023 to January 2027

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

Who is the main contact?
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Additional identifiers

Study information

Scientific Title
Prognosis of early stent thrombosis of new-generation drug-eluting stents in a contemporary setting

Acronym
PESTOND

Study objectives
The PESTOND study will evaluate the incidence and prognosis of patients with early stent thrombosis (EST) after being fitted with a new-generation drug-eluting stent (DES). The results of the present study will provide insight into the management of EST after new-generation DES in a contemporary setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted 31/10/2022, Ethics Committee of Beijing Chaoyang Hospital (No.8, Gongti South Road, Chaoyang District, Beijing, China; +86 (0)10 85231484; cyylunli2019@163.com), ref: none provided

Primary study design
Observational

Study design
Observational multicenter cohort study

Study type(s)
Other

Health condition(s) or problem(s) studied
Early stent thrombosis

Interventions
Eligible patients who were admitted at the centers between January 1st 2016 and January 1st 2022 were recruited. The following brief protocol was conducted using telephone interviews:
1. Check the identity information of the patients with them or their family members
2. Ask patients or their family members whether they have regularly taken medication (aspirin, clopidogrel, ticagrelor, statin, angiotensin-converting enzyme inhibitors, beta-blockers, calcium channel blockers) after discharge
3. Ask patients or their family members whether they have been admitted to other hospitals due to recurrent symptoms such as chest pain, chest tightness and palpitation, and whether they have received revascularization including PCI and/or CABG.

Detailed data of the categories shown below will be collected from hospital records by two independent research personnel:
1. Demographic variables (age, gender, and body mass index), cardiovascular risk factors (hypertension, diabetes mellitus, hyperlipidemia, smoking status and family history of coronary artery disease), history of cardiovascular, cerebrovascular and other chronic diseases (previous percutaneous coronary intervention [PCI], previous coronary artery bypass graft surgery, previous MI, previous stroke, chronic pulmonary disease, chronic renal insufficiency)
2. Clinical presentation (stable angina, unstable angina, non-ST-segment elevation myocardial infarction, and ST-segment elevation myocardial infarction), laboratory findings (troponin I, creatine kinase isoenzyme MB, brain-type natriuretic peptide, lactic acid, total cholesterol, triglyceride, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, uric acid, creatinine, white blood cells, hemoglobin, platelet) and left ventricular ejection fraction at the time of index procedure
3. Lesion characteristics (target lesion location, multivessel disease, bifurcation lesion, lesion in coronary ostium, severe calcification, severe tortuosity, chronic total occlusion) and procedure characteristics (total number of stent, mean stent diameter, mean stent length, post-balloon pressure, utilization of intra-aortic balloon pump, thrombus aspiration, intravascular ultrasound guidance and glycoprotein IIb/IIIa inhibitor, pre-and post-procedure Thrombolysis In Myocardial Infarction flow) of the index PCI procedure
4. Clinical presentation, laboratory findings, left ventricular ejection fraction and status of

anticoagulation and antiplatelet therapy at the time of early stent thrombosis (EST)
5. Treatment characteristics (plain balloon angioplasty, drug-eluting balloon, additional stent, additional stent number, diameter and length, emergent coronary artery bypass graft surgery, utilization of intra-aortic balloon pump, thrombus aspiration, intravascular ultrasound guidance and glycoprotein IIb/IIIa inhibitor, anticoagulation and antiplatelet therapy) for EST

Intervention Type
Mixed

Primary outcome(s)
Major adverse cardiovascular events (MACE) measured using telephone interviews with the patients or their family members, and by interrogating hospital or outpatient clinic records at five years follow-up

Key secondary outcome(s)
1. Cardiac death measured using telephone interviews with the patients or their family members, and by interrogating hospital or outpatient clinic records at five years follow-up
2. Recurrent definite stent thrombosis measured using telephone interviews with the patients or their family members, and by interrogating hospital or outpatient clinic records at five years follow-up
3. Stroke measured using telephone interviews with the patients or their family members, and by interrogating hospital or outpatient clinic records at five years follow-up

Completion date
01/01/2028

Eligibility

Key inclusion criteria
Patients who suffered from definite early stent thrombosis (EST) (defined as angiographically confirmed ST) after the index percutaneous coronary intervention with new-generation drug-eluting stent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who encounter late stent thrombosis (LST) and very late stent thrombosis (VLST)
2. Patients who experience probable stent thrombosis (ST; defined as any unexplained death within 30 days of percutaneous coronary intervention or any myocardial infarction that is related to documented acute ischemia in the territory of the implanted stent without angiographic

confirmation of stent thrombosis and in the absence of any other obvious cause) or possible ST (defined as any unexplained death from 30 days after intracoronary stenting until end of trial follow-up)
3. Patients with ST that occurs in a vein graft culprit
4. Patients treated with bare-metal stents (BMS) and/or first-generation DES at the index procedure

Date of first enrolment
01/01/2023

Date of final enrolment
01/01/2027

Locations

Countries of recruitment
China

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Scientific Research Department of Beijing Chaoyang Hospital

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Funder type
Government

Funder Name
Clinical Incubation Program of Beijing Chaoyang Hospital

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

Results and Publications

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