

Helping people who have had heart stents who are having surgeries that aren't related to the heart, using Perioperative Bridging Therapy

Submission date 08/12/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/12/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/04/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Not much information is available about the safety of using low-molecular-weight heparin (LMWH) as a bridging therapy for surgery performed more than 12 months after stent implantation. The randomized trial was set up to assess and compare the positive and negative effects of stopping antiplatelet drugs while using LMWH bridging therapy.

Who can participate?

Patients aged 75 years or older, who had a heart stent in the last 12 months, received antiplatelet therapy for 1 year or longer, and were undergoing elective surgery or other elective invasive procedure that required interruption of antiplatelet therapy

What does the study involve?

Patients were randomly assigned in equal numbers to receive either subcutaneous injections of dalteparin sodium or a placebo. The main goal was to measure the effectiveness by looking at cardiac or cerebrovascular events. The main focus on safety was to observe major bleeding.

What are the possible benefits and risks of participating?

Where is the study run from?

Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?

January 2022 to December 2024

Who is funding the study?

This study was supported by the "National Key R&D Program of China" (Funding No. 2022YFC3602405), co-funded by the National Clinical Research Center for Geriatric Diseases projects (Funding No. NCRCG-PLAGH-2023003).

Who is the main contact?
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Contact information

Type(s)

Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Funding No. 2022YFC3602405, Funding No. NCRCG-PLAGH-2023003

Study information

Scientific Title

Impact of Perioperative Bridging Therapy on clinical events of elderly patients with prior coronary stents implanted >1 year undergoing non-cardiac surgery

Acronym

IPBT

Study objectives

The safety of with low-molecular-weight heparin (LMWH) bridging therapy surgery performed >12 months from stents implantation.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 31/01/2022, Ethics Committee Of Chinese PLA General Hospital (Fuxing Road, Beijing, 100853, China; +86 10-66937166; no.email.provided@a), ref: S2022-664-03

Study design

Randomized placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied

Clinical benefits and risks of discontinuing antiplatelet drugs with LMWH bridging therapy in patients with coronary stents undergoing noncardiac surgery

Interventions

Patients were randomly assigned using an online tool to receive LMWH bridging therapy with dalteparin sodium (2500 IU administered subcutaneously twice daily) or to receive no bridging therapy (a matching subcutaneous placebo).

All study outcomes were assessed 30 days after the procedure.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

dalteparin sodium

Primary outcome(s)

Primary efficacy outcome:

Composite of major adverse cardiac or cerebrovascular events, defined as myocardial injury, myocardial infarction, cardiac death and non-fatal stroke measured using patient records at the end of the study

Primary safety outcome:

Major bleeding defined by one or more of the events defined by the International Society on Thrombosis and Haemostasis measured using patient records at the end of the study

Key secondary outcome(s)

Secondary efficacy outcomes:

Pulmonary embolism, deep-vein thrombosis and death measured using patient records at the end of the study

Secondary safety outcome:

Minor bleeding measured using patient records at the end of the study

Completion date

31/12/2024

Eligibility

Key inclusion criteria

1. 75 years of age or older
2. Underwent PCI with stents >12 months
3. Had received antiplatelet therapy for 1 year or longer
4. Were undergoing elective surgery or other elective invasive procedure that required interruption of antiplatelet therapy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Lower age limit

75 years

Sex

All

Total final enrolment

2476

Key exclusion criteria

1. Less than 75 years of age
2. Have taken antiplatelet therapy for less than 12 months
3. Were scheduled for local anesthesia surgery, planned cardiac surgery
4. Major cardiac ischemic events and/or bleeding within the previous 6 weeks
5. Patients with a mechanical heart valve, some of whom were receiving both oral anticoagulant therapy and antiplatelet therapy
6. Platelet count of less than 100×10^3 per cubic millimeter.

Date of first enrolment

01/01/2023

Date of final enrolment

01/11/2023

Locations**Countries of recruitment**

China

Study participating centre

Chinese PLA General Hospital

Fuxing Road 28

Beijing
China
100853

Sponsor information

Organisation

Chinese PLA General Hospital

ROR

<https://ror.org/04gw3ra78>

Funder(s)

Funder type

Government

Funder Name

National Key Research and Development Program of China

Alternative Name(s)

, National Basic Research Program of China (973 Program), Special Fund for the National Key Research and Development Plan, China National Key Research and Development Plan Project, National Key Research and Development of China, National Key Research and Development Program, National Key R&D Program of China, National Key R&D Programmes of China, China's National Key R&D Programmes, National Basic Research Program of China, 973 Program, National Program on Key Basic Research Project (973 Program), National Plan on Key Basic Research and Development, National Basic Research Program, NKRDP, NKPs

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

China

Funder Name

National Clinical Research Center for Geriatric Diseases

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during hte current study will be stored in a non-publicly available repository.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/04/2024	24/04/2024	Yes	No