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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

Registration date
12/12/2023

Overall study status
Completed

Last Edited
24/04/2024

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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?
Prof Linggen Gao, gaolinggen@163.com

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
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 Hosptial (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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet

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

Pharmaceutical study type(s)
Dose response

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
dalteparin sodium

Primary outcome measure
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

Secondary outcome measures
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

Overall study start date
31/01/2022

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

Age group
Senior

Lower age limit
75 Years

Sex
Both

Target number of participants
2,500

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 100×1^3 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

Sponsor details
Fuxing Road
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Sponsor type
Hospital/treatment centre

Website
http://www.301hospital.com.cn/en2012/web/Introduction.html

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, NKRDPC, 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

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

Intention to publish date
31/01/2024

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