

Efficacy and safety of prolonged use of aspirin or rivaroxaban after surgery for hip fractures

Submission date 22/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/08/2019	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Venous thromboembolism (VTE) is a condition in which a blood clot forms most often in the deep veins of the leg, groin or arm (known as deep vein thrombosis, DVT) and travels in the circulation, lodging in the lungs (known as pulmonary embolism, PE). Together, DVT and PE are known as VTE - a dangerous, potentially deadly medical condition. VTE is a serious complication with a high incidence during and after hospitalization, and it is also an important factor in deaths before and after surgery and unexpected deaths in hospitals. In patients who undergo hip fracture surgery, it is recommended that the duration of drug prevention be at least 10 days and extendable to 11–35 days. Several studies have shown that extended prophylaxis substantially reduces the risk of VTE and recommend a longer prophylaxis duration in all patients undergoing hip fracture surgery. This study compares the use of aspirin and rivaroxaban for the prevention of blood clots following hip surgery.

Who can participate?

Patients with hip fracture who require surgery.

What does the study involve?

All patients were given enoxaparin after the operation and returned to a routine dose the next day until postoperative day five. The patients in the aspirin group received an additional 16 days of thromboprophylaxis with 100 mg of aspirin once daily. The rivaroxaban group was assigned to receive an additional 16 days of thromboprophylaxis with 10 mg of oral rivaroxaban once daily.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Chengdu Fifth People's Hospital, Chengdu, China

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

November 2011 to March 2018

Who is funding the study?
Investigator funded

Who is the main contact?
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Contact information

Type(s)
Public

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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
Comparison of the efficacy and safety of aspirin and rivaroxaban following enoxaparin treatment for prevention of VTE after hip fracture surgery

Acronym

CESARFETPVTEHFS

Study objectives

Aspirin may have equal efficiency and safety with the direct oral anticoagulant rivaroxaban for the prevention of venous thromboembolism after hip fracture surgery

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 16/09/2011, Medical Ethics Committee of Chengdu Fifth People's Hospital (No. 56 Wanchun East Road, Wenjiang District, Chengdu, Sichuan Province, China; 028-82783867; cdwyiec@163.com), ref: 2019075101

Study design

Interventional pseudorandomised trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Prevention of venous thromboembolism after hip fracture surgery

Interventions

The patients were divided into the aspirin group and rivaroxaban group according to odd or even number of the end of the registration number. All patients were given enoxaparin subcutaneous injection after the operation and returned to a routine dose the next day until postoperative day 5. The patients in the aspirin group received an additional 16 days of thromboprophylaxis with 100 mg of aspirin once daily. The rivaroxaban group was assigned to receive an additional 16 days of thromboprophylaxis with 10 mg of oral rivaroxaban once daily.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Aspirin, rivaroxaban

Primary outcome measure

1. Adjudicated venous thromboembolism, which was defined as deep vein thrombosis involving the inferior vena cava to popliteal vein or pulmonary embolism. Ultrasonography of the lower extremity vein is a routine examination. All patients had to be examined before and after surgery. Pulmonary embolism was confirmed by computed tomographic pulmonary angiography, when the patient's symptoms are suspected to be a pulmonary embolism.
2. The primary safety outcome was bleeding, including major or clinically relevant nonmajor bleeding, according to Anderson's criteria. Patients were followed for 90 days regarding venous thromboembolism and bleeding complications.

Secondary outcome measures

Incidence of health issues in the 90 days following the intervention:

1. Death
2. Myocardial infarction
3. Stroke
4. Wound infection.

Overall study start date

08/09/2011

Completion date

31/03/2018

Eligibility

Key inclusion criteria

1. Hip fracture who were diagnosed by X-ray and/or computed tomography.

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Aspirin group (n=198 patients); Rivaroxaban group (n=192 patients)

Key exclusion criteria

1. Lower extremity DVT confirmed by preoperative ultrasonography
2. History of thromboembolic disease and undergoing anticoagulant therapy
3. Presence of hemorrhagic diseases and/or a major bleeding history
4. Severe liver or kidney diseases
5. Coagulation disorders
6. Allergy to enoxaparin, aspirin, or rivaroxaban
7. Platelet count less than 100×10^9 cells/L

Date of first enrolment

12/11/2011

Date of final enrolment

02/01/2018

Locations

Countries of recruitment

China

Study participating centre**Chengdu Fifth People's Hospital**

No.33 Ma-shi street

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Sponsor information

Organisation

Department of Orthopedic Surgery, West China Hospital, Sichuan University

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Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/007mrxy13>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

The intention is to publish the results of this study, in peer-reviewed journals. The results will be made available online, if permitted by journal policies.

Intention to publish date

01/10/2019

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

IPD sharing plan summary

Available on request