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Effects of a foot pump on the incidence of deep vein thrombosis after total knee arthroplasty in patients given edoxaban

Submission date 29/06/2016	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/07/2016	**Overall study status** Completed	
Last Edited 22/09/2017	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Joint diseases, including osteoarthritis (in which the protective cartilage on the end of bones wears away) and rheumatoid arthritis (in which the immune system attacks the body's own healthy joints) is a major cause of knee replacement surgery. In this type of operation, the diseased cartilage and bone is removed from the surface of the knee joint and replaced with a man-made surface of metal or plastic. This can greatly reduce disability in patients, helping them to enjoy a better quality of life. When a person undergoes the procedure, they often spend a lot of time in bed, putting them at risk of deep vein thrombosis (DVT). DVT is where a blood clot develops in a deep vein in one or both of the legs, causing pain, swelling and long term complications such as leg ulcers. If a DVT is not treated, then there is a risk that part of the blood clot could break off and become stuck in one of the lungs, blocking blood supply (pulmonary embolism, PE). Together, these two conditions are known as venous thromboembolism (VTE), which is a leading cause of death and disability worldwide. Mechanical devices such as the venous foot pump (which helps to pump blood back towards the heart, preventing it from pooling in veins) have been shown to be effective at preventing DVT. The aim of this study is to investigate the effectiveness of using a foot pump to prevent DVT in patients having knee replacement surgery.

Who can participate?
Adults aged 20 years and over who are having knee replacement surgery because of a joint disease.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given edoxaban (an anti-clotting drug) 12 hours after their surgery only. Those in the second group are given edoxaban as well as use of a foot pump. The foot pump machine is attached to slippers which are worn on the feet, to stimulate circulation. The slippers are placed on both feet in the recovery room and nurses are advised to turn on whenever the patient is sitting/lying down. Nurses routinely monitor the pressure provided by the foot pump every three hours until four days after surgery. Participants in both groups wear compression stocking (tight stockings which

squeeze the legs to prevent blood pooling in veins) on both legs after surgery. Participants are then followed up after 10 days, when they have an ultrasound scan of their legs to check for DVT. After 28 days, participants have a CT scan to check for PE.

What are the possible benefits and risks of participating?
There are no notable benefits or risks involved with participating in this study.

Where is the study run from?
NHO Nagasaki Medical Center (Japan)

When is the study starting and how long is it expected to run for?
September 2011 to May 2015

Who is funding the study?
Japanese National Hospital Organization (Japan)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of a foot pump on the incidence of deep vein thrombosis after total knee arthroplasty in patients given edoxaban: a randomized controlled study

Acronym
NHO-FPDVT

Study objectives
Use of a foot pump affects the postoperative DVT incidence under thromboprophylaxis in patients receiving TKA.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Japanese National Hospital Organization (NHO) Nagasaki Medical Center, 05/09/2011, ref: 2011/23033

Study design
Randomized control study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Deep vein thrombosis

Interventions
Participants are randomized to one of two groups (foot pump or without foot pump). Randomization is performed on the day before the operation using sealed envelopes containing a slip indicating the allocation, derived from a computer-generated sequence.

Group 1: Patients are given edoxaban starting 12 hours after their operation. Patients are given low-dose edoxaban (15 mg once daily for patients <60 kg) or high-dose edoxaban (30 mg once daily for patients weighing ≥60 kg).

Group 2: Patients are given edoxaban starting 12 hours after their operation. Patients are given low-dose edoxaban (15 mg once daily for patients <60 kg) or high-dose edoxaban (30 mg once daily for patients weighing ≥60 kg), plus use of the foot pump. Foot pump slippers are fitted on both feet in the recovery room, and the machine activated. The nurses are advised to activate the foot pump whenever the patient is not bearing weight. The nurses routinely monitor the use of mechanical compression by checking it every 3 hours until postoperative day four. An alarm is also set to sound when the foot pump turned off or pressure did not appear. The pneumatic compression cycle is set at 20/min with a pressure of 130 mmHg applied for 1 second.

All patients wear bilateral knee-high anti-thromboembolic stockings for the prevention of deep vein thrombosis.

Participants in both groups are followed up after 10 days to determine DVT rate via ultrasonography, and after 28 days to determine pulmonary embolism (PE) rat via computed tomography.

Intervention Type
Biological/Vaccine

Primary outcome measure
1. Symptomatic DVT rate is detected by ultrasonography at baseline and 10 days postoperative
2. Non-symptomatic DVT rate is detected by ultrasonography at baseline and 10 days postoperative
3. Fatal/nonfatal pulmonary embolism (PE) rate is detected by computed tomography at baseline and 28 days postoperative

Secondary outcome measures
No secondary outcome measures

Overall study start date
05/09/2011

Completion date
31/05/2015

Eligibility

Key inclusion criteria
1. Adults aged 20 and over
2. Undergoing knee replacement surgery for primary joint disease, including osteoarthritis (OA) and rheumatoid arthritis (RA)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Presence of predefined risk factors for bleeding, coagulation disorders, heart failure (New York Heart Association class III or IV), significant renal dysfunction (creatinine clearance <30mL /min)
2. Abnormalities in biochemical measurements (aspartate aminotransferase or alanine aminotransferase ≥5 times the upper limit of normal or total bilirubin ≥2 times the upper limit of normal)
3. Those scheduled to undergo bilateral joint replacement or reoperation
4. Unable to walk
5. Uncontrolled cardiovascular disease

Date of first enrolment
24/01/2012

Date of final enrolment
23/03/2015

Locations

Countries of recruitment
Japan

Study participating centre
NHO Nagasaki Medical Center
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Sponsor information

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Japanese National Hospital Organization

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03ntccx93

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Japanese National Hospital Organization

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
01/02/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/07/2016	08/07/2016	No	No
Results article	results	25/08/2016		Yes	No