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Evaluating the benefits of stocking and heparin in DVT prevention

Submission date
27/01/2016

Recruitment status
No longer recruiting

Registration date
27/01/2016

Overall study status
Completed

Last Edited
16/02/2023

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
When a person is in hospital for an operation, 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. The importance to preventing patients from developing VTE is widely recognized. The main strategies in place involve anticoagulant medications (which thin the blood so it cannot form the harmful clots) and mechanical devices such as elasticated compression stockings (which apply continuous pressure to the legs, helping to maintain bloodflow). Evidence for using elastic stockings to prevent VTE has been challenged, with a lack of evidence for the additional benefits of elastic stockings over and above the benefit of blood-thinning. If elastic stockings reduce VTE over and above blood thinners, these benefits need to be weighed against the disadvantages, such as discomfort, restricting blood flow to the leg, blistering, cost and staff needing to help patients to put them on. The aim of this study is to look at whether patients who wear elastic stockings as well as taking anticoagulant medication have a lower chance of developing VTE than patients who take anticoagulant medications only.

Who can participate?
Adults who are having surgery at a participating hospital, who are at risk of developing VTE.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given graduated compression stockings (specially designed compression stockings where the pressure is at the highest level around the ankle and becomes lower further up the leg) to wear during their hospital stay, as well as taking low molecular weight heparin (anticoagulant medication especially for treating VTE), the dosage of this is determined by each patients' individual characteristics. Participants in the second group take low molecular weight heparin only. Participants attend follow up appointments after 1 and 2-3 weeks, as well as 90 days after

surgery, to have their legs scanned to check for the presence of any blood clots. Participants also complete a number of questionnaires in order to find out if their quality of life has improved.

What are the possible benefits and risks of participating?
There are no direct benefits of taking part as the treatments given (i.e. heparin plus stockings) are already provided in standard care. Participants benefit from receiving a scan for the presence of DVT in this study and so are able to receive treatment. There are no significant risks of taking part, however some participants may experience some side-effects from the medication or may find the compression stockings uncomfortable at first as they are very tight.

Where is the study run from?
At least seven NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for?
December 2015 to November 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Rebecca Lawton, r.lawton@imperial.ac.uk (from 26/04/2018)
Miss Francine Heatley, f.heatley@imperial.ac.uk (before 26/04/2018)

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20354

Study information

Scientific Title
Examining the benefit of graduated compression stockings as an adjunct to low dose low molecular weight heparin in the prevention of venous thromboembolism in elective surgical inpatients identified as moderate or high risk for venous thromboembolism: A multi-centre randomised controlled trial

Acronym
GAPS

Study objectives
The aim of this study is to investigate whether treatment with elastic compression stockings and blood thinning medicines combined are more effective at preventing venous thromboembolism (VTE) than blood-thinning medicines alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
REC: London - City Road & Hampstead Research Ethics Committee, 08/02/2016, ref: 16/LO/0015

Study design
Pragmatic, multicentre randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Venous thromboembolism

Interventions
Participants are randomly allocated using a computer to one of two groups.

Group 1: Participants are treated with low molecular weight heparin (LMWH) as per standard clinical recommendations (dosing regimen depending on participant characteristics). These patients are also given either below- or above-knee graduated compression stockings (GCS) to wear as per advice of the treating clinician.

Group 2: Participants are treated with low molecular weight heparin (LMWH) alone as per standard clinical recommendations (dosing regimen depending on participant characteristics).

Participants in both groups are followed up 1, between 2 and 3 weeks and 90 days after surgery to receive duplex scanning checking for the presence of blood clots.

Intervention Type
Other

Primary outcome measure
Presence of VTE within 90 days of surgery is measured using duplex ultrasound scanning of lower limbs 1, 2-3 weeks and 90 days post surgery.

Secondary outcome measures
1. Compliance with stockings and LMWH is determined at 90 days
2. Overall mortality is determined at 90 days
3. Quality of life is measured using the EQ5D questionnaire at 90 days

Overall study start date
01/12/2015

Completion date
30/11/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 26/04/2018:
1. Aged 18 years or over (from Jan 2018 recruitment will be restricted to patients aged 65 years and above)
2. Capacity to provide informed consent
3. Elective surgical inpatients at a participating hospital
4. Moderate or high risk of venous thromboembolism (VTE)

Previous inclusion criteria:
1. Aged 18 years or over
2. Capacity to provide informed consent
3. Elective surgical inpatients at a participating hopsital
4. Moderate or high risk of venous thrombo-embolism (VTE)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2236; UK Sample Size: 2236

Total final enrolment
1905

Key exclusion criteria
1. Contraindications to low molecular weight heparin (LMWH)
2. Contraindications to graduated compression stockings (GCS), including peripheral arterial disease, stroke patients,
individuals undergoing lower limb surgery
3. Documented or known thrombophilia or thrombogenic disorder
4. Individuals requiring therapeutic anticoagulation
5. Previous venous thrombo-embolism (VTE)
6. Patients having intermittent pneumatic compression (IPC) beyond theatre and recovery
7. Patients requiring inferior vena cava (IVC) filter
8. Pregnancy
9. Patients requiring extended thromboprophylaxis
10. Application of a cast or brace in theatre

Date of first enrolment
01/05/2016

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Charing Cross Hospital
Fulham Palace Road
London
United Kingdom
W6 8RF

Study participating centre
Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University Hospital Southampton
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Lode Lane
Solihull
United Kingdom
B91 2JL

Study participating centre
Portsmouth Hospitals NHS Trust
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation

Imperial College London

Sponsor details
Joint Research Compliance Office
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Planned publication and presentation of results at scientific meetings
2. Summaries of results will also be made available to Investigators for dissemination within their clinical areas (where appropriate and according to their discretion)
3. There will also be an online dissemination plan, with participants and healthcare professionals

able to access results on a trial website, and appropriate use of social media (Twitter, Facebook, LinkedIn)
4. Trial participants will also be offered a mailed summary of the trial findings

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2017		Yes	No
Results article	results	13/05/2020	10/06/2020	Yes	No
Results article	results	01/12/2020	07/12/2020	Yes	No
Plain English results			16/02/2023	No	Yes
HRA research summary			28/06/2023	No	No