ISRCTN44653506 https://doi.org/10.1186/ISRCTN44653506

The PREVENT trial: pneumatic compression for preventing venous thromboembolism

Submission date
22/07/2013

Recruitment status
No longer recruiting

Registration date
30/10/2013

Overall study status
Completed

Last Edited
06/03/2023

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
Despite improvement in the prevention of thrombosis (thromboprophylaxis), venous thromboembolism (VTE) remains a common problem in critically ill patients. Patients admitted to the intensive care unit are at high risk of developing clots in the veins of the lower extremities. The objective of this study is to examine whether the use of a device that provides intermittent pneumatic compression (IPC) to the legs in addition to the use of low-dose blood thinners (also called heparin thromboprophylaxis) provides an additional protection when compared to the use of blood thinners alone.

Who can participate?
Patients who are admitted to the intensive care unit are receiving low-dose blood thinners to prevent clots are candidate for this study.

What does the study involve?
Patients will be randomly allocated to one of two groups: all will receive blood thinners but some will additionally receive the leg compression.

What are the possible benefits and risks of participating?
The additional use of leg compression may provide protection from clots. The main side effect is possible skin abrasions but this is usually mild.

Where is the study run from?
The study will be conducted in several hospitals in Saudi Arabia, Canada, USA, India, and possibly other countries.

When is the study starting and how long is it expected to run for?
The study is planned to start in December 2013 and to continue for 4 years.

Who is funding the study?
King Abdullah International Medical Research Center (KAIMRC), Riyadh, Saudi Arabia.

Who is the main contact?
Each hospital will have a contact person but the main contact will be Dr Yaseen Arabi, yaseenarabi@yahoo.com.

Contact information

Type(s)
Scientific

Contact name
Dr Yaseen Arabi

Contact details
King Saud Bin Abdulaziz University for Health Sciences
King Abdulaziz Medical City
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11426

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02040103

Secondary identifying numbers
RC 12/045

Study information

Scientific Title
Prophylaxis of thromboembolism in critically ill patients using combined intermittent pneumatic compression and pharmacologic prophylaxis versus pharmacologic prophylaxis alone: a multicenter randomized controlled trial

Acronym
PREVENT

Study objectives
Patients having pharmaceutical and mechanical prophylaxis will have better outcomes than patients having pharmaceutical prophylaxis alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Ethics Board: National Guard Health Affairs Institutional Review Board, Ref # IRBC/149/13, 18/06 /2013

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Intensive care unit, critically ill patients, VTE prophylaxis

Interventions
Intermittent pneumatic compression combined with pharmacologic prophylaxis compared to pharmacologic prophylaxis.

Patients will be randomized into one of the two intervention arms:
1. Treatment group: IPC and pharmacological thromboprophylaxis
2. Control group: pharmacological thromboprophylaxis alone

The study interventions will continue for the duration of the ICU stay or up to 30 days in ICU. Upon discharge from the ICU or 30 days in ICU, thromboprophylaxis will be at the discretion of treating team.

Patients will be followed daily until discharge from ICU or 30 days.

Intervention Type
Mixed

Primary outcome measure
Primary outcome measure as of 04/11/2017:
Incidence of proximal leg deep vein thrombosis (DVT) will be followed up to 28 days post randomization.

Original primary outcome measure:
Incident proximal leg deep vein thrombosis (DVT) will be followed up to 30 days

Secondary outcome measures
Secondary and tertiary outcome measure as of 04/11/2017:
Secondary outcomes:
1. Pulmonary Embolism: will be followed up to ICU discharge or day 28
2. ICU Mortality. Death in ICU during the same ICU admission
3. Hospital Mortality. Death in the hospital (in ICU or on ward) during the same hospital admission. (Hospital mortality will be censored at 1 year from the date of enrollment). 30-day Mortality: Death before or at day 30 of enrollment. 90-day Mortality: Death before or at day 90 of enrollment

Tertiary outcomes:
1. ICU Length of Stay: Number of calendar days between admission and discharge from ICU
2. Duration of Mechanical Ventilation: Number of calendar days between start and end of mechanical ventilation

Original secondary and tertiary outcome measures:
Secondary outcomes:
1. Pulmonary Embolism: will be followed up to ICU discharge or day 30
2. ICU Mortality. Death in ICU during the same ICU admission
3. Hospital Mortality. Death in the hospital (in ICU or on ward) during the same hospital admission. (Hospital mortality will be censored at 1 year from the date of enrollment). 30-day Mortality: Death before or at day 30 of enrollment. 90-day Mortalit: Death before or at day 90 of enrollment

Tertiary outcomes:
1. ICU Length of Stay: Number of calendar days between admission and discharge from ICU
2. Duration of Mechanical Ventilation: Number of calendar days between start and end of mechanical ventilation

Overall study start date
01/12/2013

Completion date
31/12/2018

Eligibility

Key inclusion criteria
All patients (male + female) admitted to ICU will be screened for eligibility
1. Medical-Surgical ICU patients >14 years old
2. Weight > 45 kg
3. Expected ICU LOS> 72 hours
4. Eligible for pharmacologic thromboprophylaxis with UFH and LMWH

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2000

Total final enrolment
2003

Key exclusion criteria
Exclusion criteria as of 04/04/2017:
1. Patient treated with IPC for > 24 hours in this current ICU admission.
2. Patient in the ICU> 48 hours.
3. Patient treated with pharmacologic VTE prophylaxis with medications other than UFH or LMWH.
4. Inability or contraindication to applying IPC to both legs or to obtain adequate ultrasound on the lower extremities
4.1. Burns in the lower extremities, lacerations, active skin infection, & ischemic limb in the legs, large dressings at the site of IPC placement or in the thighs that prevent adequate ultrasounds
4.2. Acute ischemia in the lower extremities
4.3. Amputated foot or leg on one or two sides
4.4. Compartment Syndrome
4.5. Severe peripheral arterial disease
4.6. Vein ligation, gangrene, recent vein grafts, and draining incisions
4.7. Evidence of bone fracture in lower extremities
4.8. Arterial lines in the dorsalis pedis artery
5. Therapeutic dose of anticoagulation with UFH or LMWH
6. Pregnancy
7. Limitation of life support, life expectancy < 7 days or palliative care
8. Allergy to the sleeves material
9. Patients with Inferior Vena Cava (IVC) Filter

Eligible Non-Randomized Criteria
1. Patient or substitute decision maker declines consent but agrees to minimal data set collection
2. Unable to get consent within 48 hours of ICU admission
3. ICU physician or other treating clinician declines consent
4. Co-enrollment in trials with biologic interaction

Original exclusion criteria:
1. Patient on IPC for > 24 hours in this current ICU admission
2. Patient on pharmacologic prophylaxis with medications other than UFH or LMWH
3. Inability or contraindication to applying IPC to both legs:
3.1. Burns in the lower extremities, lacerations, active skin infection, & ischemic limb in the legs at the site of IPC placement
3.2. Acute ischemia in the lower extremities
3.3. Amputated foot or leg on one or two sides
3.4. Compartment Syndrome

3.5. Severe peripheral arterial disease
3.6. Vein ligation, gangrene, recent vein grafts, and draining incisions
3.7. Evidence of bone fracture in lower extremities
4. The need for therapeutic anticoagulation
5. Pregnancy
6. Limitation of life support, life expectancy < 7 days or palliative care
7. Allergy to the sleeves material

Date of first enrolment
14/07/2014

Date of final enrolment
13/08/2018

Locations

Countries of recruitment
Australia

Brazil

Canada

India

Saudi Arabia

Study participating centre
King Abdulaziz Medical City
Ministry of National Guard Health Affairs (MNGHA)
Prince Mutib bin Abdullah Street
Riyadh
Saudi Arabia
11426

Study participating centre
Royal North Shore Hospital
Reserve Road
St Leonards
Australia
NSW 2065

Study participating centre
Saint Michael's Hospital
30 Bond Sreet

Toronto
Canada
M5B 1W8

Study participating centre
Medanta, The Medicity
Sector 38
Gurugram
Haryana
India
122001

Study participating centre
Hospital do Coracao
R. Des. Eliseu Guilherme
147 - Paraíso
São Paulo
Brazil
04004-030

Sponsor information

Organisation
King Abdullah International Medical Research Center

Sponsor details
Ministry of National Guard Health Affairs (MNGHA)
Prince Muteb bin Abdullah Street
Riyadh
Saudi Arabia
11426
+966 (0)11 429 4502
kaimrc@ngha.med.sa

Sponsor type
Hospital/treatment centre

Website
https://www.kaimrc.med.sa

ROR
https://ror.org/009p8zv69

Organisation
King Abdulaziz City for Science and Technology

Sponsor details
King Abdullah Road (West)
Riyadh
Saudi Arabia
12371
+966 (0)11 429 4502
gdrgp@kacst.edu.sa

Sponsor type
Research organisation

Website
https://www.kacst.edu.sa

ROR
https://ror.org/05tdz6m39

Funder(s)

Funder type
Research organisation

Funder Name
King Abdullah International Medical Research Center

Alternative Name(s)
KAIMRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Saudi Arabia

Results and Publications

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

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	03/08/2016		Yes	No
Results article	results	04/04/2019		Yes	No
Results article	sub-study results	01/04/2020	26/02/2020	Yes	No
Results article	Secondary analysis	20/05/2022	23/05/2022	Yes	No
Other publications	Post hoc analysis	03/03/2023	06/03/2023	Yes	No