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The effect of pneumatic compression stockings in haemodialysis patients: a randomised crossover trial

Submission date	Recruitment status	[ ] Prospectively registered
12/11/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/12/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
23/12/2008	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of pneumatic compression stockings on haemodynamic parameters in haemodialysis patients: a randomised crossover trial

Study objectives
Primary hypothesis:
To determine the effect of pneumatic compression devices (PCDs), compared to standard of care, on central blood volume in both intradialytic hypotension (IDH) prone and non-IDH prone haemodialysis patients.

Secondary hypothesis:
To determine the effect of PCDs on the haemodynamic response during haemodialysis in both IDH-prone and non-IDH prone patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Calgary Office of Medical Bioethics approved on 2nd October 2008 (ref: ED-21937)

Study design
Randomised single centre active-controlled crossover 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
End-stage kidney disease on haemodialysis

Interventions
For sequence 1, the patient will undergo three HD sessions with PCDs, followed by three HD sessions without PCDs. For sequence 2, the patient will undergo three HD sessions without PCDs, followed by three sessions with PCDs. PCDs will be applied firmly around the calves prior to the initiation of HD with compressions intermittently applied at 40 mmHg throughout HD

sessions. Frequencies of the compressions will be three cycles of compressions and decompressions per minute. Each cycle of compression and decompression will last approximately ten seconds. Lower extremities of all patients will be kept horizontal during the dialysis run.

The total duration of treatment is three consecutive HD sessions at 4 hours each; the follow up period is the same.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The change in central blood volume with and without PCDs in both IDH-prone patients and non-IDH prone patients. Central blood volume will be determined using ultrasound dilution technique as per standard procedures. Determined within the first 30 minutes of HD and again within the last 15 minutes of the HD session; this is done for each of the study HD sessions (three with treatment, three with control).

Secondary outcome measures
Determined within the first 30 minutes of HD and again at the last 15 minutes of HD for each of the study sessions:
1. Cardiac output
2. Mean arterial pressure
3. Bioimpedance derived extracellular fluid (ECF) and intracellular fluid (ICF) values

Overall study start date
01/12/2008

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Chronic stable HD patients who have been on HD at least three times per week for at least 3 months
2. Both males and females, aged 18 - 95 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
51

Key exclusion criteria
1. Dialysing with a central venous catheter
2. Vascular access dysfunction
3. Lower extremity arterial ulcers, severe peripheral arterial disease, lower extremity amputations
4. Active medical issues
5. Unable to provide informed consent

Date of first enrolment
01/12/2008

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Canada

Study participating centre
Foothills Medical Centre
Calgary
Canada
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Sponsor information

Organisation
University of Calgary (Canada)

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Sponsor type
University/education

ROR
https://ror.org/03yjb2x39

Funder(s)

Funder type
University/education

Funder Name
University of Calgary (Canada) - Faculty of Medicine, Division of Nephrology

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration