

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

Submission date
12/11/2008

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
23/12/2008

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
23/12/2008

Condition category
Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jennifer MacRae

Contact details

Foothills Medical Centre
C210, 1403 29th Street NW

Calgary

Canada

T2N 2T9

+1 403 944 8168

jennifer.macrae@calgaryhealthregion.ca

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

T2N 2T9

Sponsor information**Organisation**

University of Calgary (Canada)

Sponsor details

c/o Jennifer MacRae

Foothills Medical Centre

Calgary Health Region

C210 1403-29th Street NW

Calgary

Canada

T2N 2T9
+1 403 944 8168
jennifer.macrae@calgaryhealthregion.ca

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