

# 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

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## Additional identifiers

### Protocol serial number

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

### **Study type(s)**

Treatment

### **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(s)**

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).

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

**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

**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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