ISRCTN22392984 https://doi.org/10.1186/ISRCTN22392984

# Randomised controlled trial of remote ischaemic pre-conditioning to reduce dialysis induced myocardial stunning in haemodialysis patients

**Submission date**
21/06/2011

**Recruitment status**
No longer recruiting

**Registration date**
21/06/2011

**Overall study status**
Completed

**Last Edited**
16/11/2017

**Condition category**
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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 Aghogho Odudu

**Contact details**
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

## Additional identifiers

**Protocol serial number**
10327

## Study information

**Scientific Title**

Randomised controlled trial of remote ischaemic pre-conditioning to reduce dialysis induced myocardial stunning in haemodialysis patients

## Acronym
RIPC

## Study objectives
Patients with kidney disease who require dialysis have an increased rate of death due to heart disease. This is partly due to the stress which dialysis places on the heart. This stress known as 'stunning' eventually leads to heart failure.

This research explores using a simple blood pressure cuff to restrict blood flow to the leg for a few minutes. This may boosts the body's protective responsive to condition the heart in a way which may protect it from stunning during dialysis. The hope is that this simple and cheap technique could be used to reduce the development of heart disease in dialysis patients. This study lasts 4 to 6 weeks per participant and requires 80 participants.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
11/EM/0037

## Study design
Randomised; Interventional; Design type: Treatment

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Cardiovascular, Renal and Urogenital

## Interventions
1. Remote pre-conditioning
2. 3 cycles of cuff inflations to 200mmHg for 5 mins
3. Follow Up Length: 1 month

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome(s)
1. Regional wall motion abnormalities on 2D-echo
2. Timepoint(s): Within 4 hours of the stimulus or sham-stimulus

### Key secondary outcome(s))
1. Change in haemodynamic variables after:
1.1. Intervention visit
1.2. First follow-up visit
1.3. Final visit
2. Frequency of intradialytic hypotension after:
2.1. Intervention visit
2.2. First follow-up visit
2.3. Final visit
3. Regional wall motion abnormalities on 2D-echo after:
3.1. First follow-up visit
3.2. Final visit
4. Troponin-T, Plasma IL-6 and N-Type proBNP after:
4.1. Intervention visit
4.2. First follow-up visit
4.3. Final visit

### Completion date
16/10/2012

## Eligibility

### Key inclusion criteria
1. Patients having haemodialysis treatment at least 3 times per week at the Royal Derby Hospital
2. Male or female
3. Lower Age Limit 16 years

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
1. Not meeting inclusion criteria
2. Exposure to haemodialysis for <90 days prior to recruitment
3. Severe heart failure (New York Heart Association grade IV)
4. Cardiac transplant recipients
5. Mental incapacity to consent
6. Declined to participate
7. Taking cyclosporin
8. Taking ATP-sensitive potassium channel opening or blocking drugs

### Date of first enrolment

16/05/2011

**Date of final enrolment**
16/10/2012

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**Royal Derby Hospital**
Derby
United Kingdom
DE22 3NE

# Sponsor information

**Organisation**
Derby Hospital NHS Foundation Trust (United Kingdom)

# Funder(s)

**Funder type**
Charity

**Funder Name**
British Heart Foundation (United Kingdom)

**Alternative Name(s)**
the_bhf, The British Heart Foundation, BHF

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Trusts, charities, foundations (both public and private)

**Location**
United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration