

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/06/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 16/11/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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 boost the body's protective response 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

16/05/2011

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 80; UK Sample Size: 80

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**

England

United Kingdom

Study participating centre

Royal Derby Hospital

Derby

United Kingdom

DE22 3NE

Sponsor information**Organisation**

Derby Hospital NHS Foundation Trust (United Kingdom)

Sponsor details

Royal Derby Hospital

Uttoxeter Road

Derby

England

United Kingdom

DE22 3NE

Sponsor type

Hospital/treatment centre

Website

<http://www.derbyhospitals.nhs.uk/>

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

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