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

Submission date
21/06/2011

Registration date
21/06/2011

Last Edited
16/11/2017

Recruitment status
No longer recruiting

Overall study status
Completed

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
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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 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

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