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Study into myocardial stunning during haemodialysis and the effect of biofeedback haemodialysis

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/06/2014	Urological and Genital Diseases	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0077122814

Study information

Scientific Title

Study objectives
1. Haemodialysis with ultrafiltration is capable of inducing myocardial stunning in individuals both with and without coronary artery disease
2. Myocardial stunning induced by haemodialysis may be ameliorated by the use of biofeedback-controlled haemodialysis, despite identical total ultrafiltration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised crossover study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
Urological and Genital Diseases: Haemodialysis

Interventions
We propose to study chronic haemodialysis patients in a randomised crossover study.
The first group will undergo an initial period of standard haemodialysis followed by a period of biofeedback-controlled haemodialysis.
The second group will do the same in reverse.
At the end of both periods, all patients will undergo echocardiography performed at regular intervals throughout a single haemodialysis session, and for a short period afterwards. They will also have Troponin T measured before and after the same dialysis session.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Number of regional wall abnormalities/patient
2. Ejection and shortening fractions

Secondary outcome measures
Not provided at time of registration

Overall study start date
21/02/2003

Completion date
01/04/2003

Eligibility

Key inclusion criteria
Patients on chronic haemodialysis

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
21/02/2003

Date of final enrolment
01/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (UK)

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