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Study into the control of blood pressure and antihypertensive medication withdrawal in haemodialysis patients by programmed reduction in dry weight

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2005	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 07/04/2014	**Condition category** Circulatory System	[_] Individual participant data [_] 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
N0077114319

Study information

Scientific Title

Study objectives
Whether or not blood pressure can be controlled safely and effectively with a protocol driven program of dry weight reduction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular: Hypertension

Interventions
We propose to study 40 patients currently undergoing chronic haemodialysis in a randomised un-blinded prospective fashion.
The first group will have their dry weight adjusted according to need as assessed at every dialysis session by nursing staff, and at monthly consultant review.
The second group will undergo a protocol driven program of dry weight reduction and antihypertensive withdrawal using the dialysis methods outlined above.
The two groups will be assessed for the effectiveness of BP reduction, ultimate reduction in dry weight, inter-dialytic weight gains, adequacy of delivered dialysis, antihypertensive use and frequency and severity of hypotensive (symptomatic or otherwise) events.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
Primary end points:
1. The number of patients attaining pre-dialysis BP < 140/90 with partial or total withdrawal of antihypertensive medication.
2. Incidence of hypotensive episodes

Secondary outcome measures
Secondary end points:
1. Correlation between satisfactory pre dialysis BP and 24 hour BP profile
2. Patient tolerability (symptoms)

Overall study start date
01/04/2005

Completion date
01/04/2006

Eligibility

Key inclusion criteria
Chronic haemodialysis patients

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

Key exclusion criteria
1. Clinical Evidence of fluid overload (peripheral or pulmonary oedema)
2. History of major cardiovascular event within the last year (myocardial infarction, CVA and major peripheral vascular disease episodes)
3. Patients having either acetate free biofiltration or haemodiafiltration
4. History of interdialytic weight gains of greater than 4 kg
5. Haemoglobin (Hb) less than 8 g/dl
6. Autonomic neuropathy

Date of first enrolment
01/04/2005

Date of final enrolment
01/04/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derby Hospitals NHS Foundation Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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SW1A 2NL
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name

Derby Hospitals NHS Foundation Trust (UK), NHS R&D Support Funding

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