

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 07/04/2014	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

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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

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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

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