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Is stepwise profiling of sodium and fluid removal during the dialysis of elderly patients clinically beneficial?

Submission date	Recruitment status	[_] Prospectively registered
23/01/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/09/2012	Urological and Genital Diseases	

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
RRCC164R XHN041

Study information

Scientific Title

Study objectives
The study propose to investigate strategies for improving haemodynamic stability during dialysis in elderly patients with a view to minimising hypotensive episodes. The study seeks to investigate the potential of controlling plasma volume during dialysis by variation of the rate of fluid removal and the rate of sodium (Na) influx from the dialysis fluid during treatment individually and in combination.

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)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Chronic renal failure; dialysis

Interventions
1. No intervention
2. Fluid removal profiling alone
3. Sodium profiling alone
4. Fluid and sodium profiling alone

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Number of nursing interventions
2. Changes in blood pressure
3. Episodes of hypotension (defined as a drop >30 mmHg systolic blood pressure)
4. At the end of each phase of the study (3 treatment sessions) patient quality of life will be assessed by the use of SF36 questionnaire, and a fatigue questionnaire as described by Prince MI. James OF. Holland NP. Jones DE. Validation of a fatigue impact score in primary biliary cirrhosis: towards a standard for clinical and trial use. Journal of Hepatology. 32(3):368-73, 2000

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/01/2000

Completion date
05/01/2001

Eligibility

Key inclusion criteria
Study will be confined to patients with chronic renal failure on regular dialysis whose age is greater than 65 years

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
10/01/2000

Date of final enrolment
05/01/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
4th Floor William Leach Building (M4,123)
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Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2002		Yes	No