

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

**Submission date**

23/01/2004

**Recruitment status**

No longer recruiting

**Registration date**

23/01/2004

**Overall study status**

Completed

**Last Edited**

18/09/2012

**Condition category**

Urological and Genital Diseases

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

**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)**

Newcastle upon Tyne

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## **Sponsor information**

**Organisation**

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

**Sponsor details**

The Department of Health

Richmond House

79 Whitehall

London

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SW1A 2NL

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dhmail@doh.gsi.org.uk

**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?
<a href="#">Results article</a>	results	01/06/2002		Yes	No