

# Study into achievement of isonatric haemodialysis by individual tailoring of dialysate sodium according to ionic mass balance derived from online conductance monitoring

**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**

16/04/2015

**Condition category**

Urological and Genital Diseases

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

**Protocol serial number**

N0077114320

# Study information

## Scientific Title

Study into achievement of isonatric haemodialysis by individual tailoring of dialysate sodium according to ionic mass balance derived from online conductance monitoring

## Study objectives

Whether or not individualising dialysate sodium has beneficial effects on haemodialysis patients interdialytic weight gains, blood pressure and thirst when compared to standard dialysate sodium.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Not provided at time of registration

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Urological and Genital Diseases: Renal dialysis

## Interventions

The two groups will both undergo a 1-week period of initial data collection while being maintained on routine dialysis. Dialysis will be performed using a default dialysate sodium of 140 mmol/l.

The first group will then continue to dialyse against a standard dialysate sodium concentration of 140 mmol/l, while the second group undergoes a period of 1 month of sequential reduction of dialysate sodium according to online conductivity monitoring, aiming for isonatric dialysis (i.e. ionic mass balance of 0-100 mmol of sodium). This will then be maintained for a period of one month.

After that time, there will be a crossover period of adjustment, during which the first group will have their dialysate sodium tailored to their requirements, and the second group will revert in a gradual manner to a dialysate sodium of 140 mmol/l.

Again the two groups will be maintained for a further month, before both groups revert to a standard dialysate sodium at the end of the study.

## Intervention Type

Other

## Phase

Not Specified

**Primary outcome(s)**

Neutral sodium balance as assessed by ionic mass balance reduction in interdialytic weight gain.

**Key secondary outcome(s)**

Pre and post dialysis blood pressure, number of anti-hypertensive agents stability on dialysis, thirst score.

**Completion date**

23/03/2004

**Eligibility****Key inclusion criteria**

Patients on routine haemodialysis

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Not Specified

**Key exclusion criteria**

No documented exclusion criteria. Protocol specifies ALL patients on established haemodialysis.

**Date of first enrolment**

23/09/2002

**Date of final enrolment**

23/03/2004

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Derby Hospitals NHS Foundation Trust

Derby

United Kingdom

DE22 3NE

# Sponsor information

## Organisation

Department of Health

## Funder(s)

### Funder type

Government

### Funder Name

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

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration