

# Study into myocardial stunning during haemodialysis and the effect of biofeedback haemodialysis

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 16/06/2014	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Contact name**  
Dr CW McIntyre

**Contact details**  
Southern Derbyshire Acute Hospitals NHS Trust  
Department of Nephrology  
Derby City General Hospital  
Uttoxeter Road  
Derby  
United Kingdom  
DE22 3NE  
+44 (0)1332 340131

## Additional identifiers

**Protocol serial number**  
N0077122814

## Study information

**Scientific Title**

**Study objectives**

1. Haemodialysis with ultrafiltration is capable of inducing myocardial stunning in individuals both with and without coronary artery disease
2. Myocardial stunning induced by haemodialysis may be ameliorated by the use of biofeedback-controlled haemodialysis, despite identical total ultrafiltration

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Primary study design**

Interventional

**Study design**

Randomised crossover study

**Study type(s)**

Not Specified

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

Urological and Genital Diseases: Haemodialysis

**Interventions**

We propose to study chronic haemodialysis patients in a randomised crossover study. The first group will undergo an initial period of standard haemodialysis followed by a period of biofeedback-controlled haemodialysis. The second group will do the same in reverse. At the end of both periods, all patients will undergo echocardiography performed at regular intervals throughout a single haemodialysis session, and for a short period afterwards. They will also have Troponin T measured before and after the same dialysis session.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

1. Number of regional wall abnormalities/patient
2. Ejection and shortening fractions

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/04/2003

## Eligibility

### Key inclusion criteria

Patients on chronic haemodialysis

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Not Specified

### Sex

Not Specified

### Key exclusion criteria

Not provided at time of registration

### Date of first enrolment

21/02/2003

### Date of final enrolment

01/04/2003

## Locations

### Countries of recruitment

United Kingdom

England

### Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust

Derby

United Kingdom

DE22 3NE

## Sponsor information

### Organisation

Department of Health (UK)

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Southern Derbyshire Acute Hospitals NHS Trust (UK)

## **Results and Publications**

### **Individual participant data (IPD) sharing plan**

#### **IPD sharing plan summary**

Not provided at time of registration