# Oxygen concentration and myocardial stunning

Submission date	Recruitment status	Prospectively registered
28/09/2010	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
09/03/2012	Stopped	Results
Last Edited	Condition category	Individual participant data
21/11/2019	Circulatory System	Record updated in last year

### Plain English summary of protocol

Not provided at time of registration

## Contact information

Type(s)

Scientific

#### Contact name

Dr Christopher McIntyre

#### Contact details

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## Additional identifiers

EudraCT/CTIS number

2007-004012-31

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RD 5130-009-07

## Study information

#### Scientific Title

The effects of improving oxygen concentration in the reduction of dialysis induced myocardial stunning - a pilot study

#### **Study objectives**

Increasing oxygen concentration by administering inhaled oxygen reduces the severity and frequency of haemodialysis induced myocardial stunning.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Trent Research Ethics Committee, 06/07/2009, ref: 09/H0405/18

#### Study design

Randomised controlled cross-over trial

#### Primary study design

Interventional

#### Secondary study design

Randomised cross over trial

#### Study setting(s)

Hospital

#### Study type(s)

Treatment

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Dialysis-induced myocardial stunning

#### **Interventions**

4 litres oxygen delivered by nasal cannulae during standard 4-hour haemodialysis.

### Intervention Type

Other

#### **Phase**

Not Applicable

#### Primary outcome measure

- 1. Myocardial stunning
- 2. Development of regional wall motion abnormalities

Key observations are taken pre-dialysis (baseline) and 15 minutes prior to end of dialysis (peak stress) by cardiac echocardiography (for later offline semi-automated analysis for regional wall motion abnormalities).

#### Secondary outcome measures

Intradialytic haemodynamics; haemodynamic variables observed pre-dialysis, and throughout dialysis treatment, with continuous non-invasive measurement by finometer, and NICOM (bioreactance).

#### Overall study start date

01/06/2010

#### Completion date

01/11/2010

#### Reason abandoned (if study stopped)

Lack of staff/facilities/resources

## Eligibility

#### Key inclusion criteria

- 1. Male and female
- 2. Over 18 years old
- 3. Chronic haemodialysis greater than 4 months

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

24

### Key exclusion criteria

- 1. Cardiac transplant
- 2. New York Heart Association (NYHA) grade IV heart failure
- 3. Chronic obstructive airways disease, other chronic/acute lung condition exacerbating hypoxia and/or unable to tolerate O2 therapy
- 4. Patient on long-term oyxgen therapy (LTOT)

#### Date of first enrolment

01/06/2010

#### Date of final enrolment

01/11/2010

## Locations

#### Countries of recruitment

England

**United Kingdom** 

Study participating centre Royal Derby Hospital

Derby United Kingdom DE22 3NE

## Sponsor information

#### Organisation

Derby Hospitals NHS Foundation Trust (UK)

### Sponsor details

Uttoxeter Road
Derby
England
United Kingdom
DE22 3NE
+44 (0)1332 347141
teresa.grieve@derbyhospitals.nhs.uk

#### Sponsor type

Hospital/treatment centre

#### Website

http://www.derbyhospitals.nhs.uk/

## Funder(s)

#### Funder type

Charity

#### **Funder Name**

Kidney Research UK

Alternative Name(s)

**Funding Body Type** 

Private sector organisation

**Funding Body Subtype** 

Other non-profit organizations

Location

United Kingdom

## **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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?HRA research summary28/06/2023NoNo