

Oxygen concentration and myocardial stunning

Submission date 28/09/2010	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 09/03/2012	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 21/11/2019	Condition category Circulatory System	☐ 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

Clinical Trials Information System (CTIS)

2007-004012-31

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled cross-over trial

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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 oxygen therapy (LTOT)

Date of first enrolment

01/06/2010

Date of final enrolment

01/11/2010

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Royal Derby Hospital

Derby

United Kingdom

DE22 3NE

Sponsor information

Organisation

Derby Hospitals NHS Foundation Trust (UK)

Funder(s)

Funder type

Charity

Funder Name

Kidney Research UK

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No