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Oxygen concentration and myocardial stunning

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

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