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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
Department of Renal Medicine
Royal Derby Hospital
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

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

Study design
Randomised controlled cross-over trial

Primary study design
Interventional

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 oyxgen 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes