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Myocardial perfusion and microvascular dysfunction in stable coronary artery disease during hyperoxaemia

Submission date 14/08/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 14/08/2014	**Overall study status** Completed	
Last Edited 21/09/2016	**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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17103

Study information

Scientific Title
Myocardial perfusion and microvascular dysfunction in stable coronary artery disease during hyperoxaemia

Study objectives
Coronary artery disease (CAD) is a leading cause of death and disability worldwide. Around 20-40% of the UK population will experience chest pain during their lifetime, accounting for 40% of acute hospital admissions. Oxygen has long been advocated as a therapeutic agent and treatment option in the management of chest pain, although the scientific basis for this is questionable and there is currently no clinical evidence to support the routine use of oxygen in the setting of myocardial ischaemia. Experimental data suggests hyperoxaemia may actually be harmful purported to be due to alteration in microvascular function. This study is divided into two parts: A. we intend to quantify myocardial blood flow with cardiovascular magnetic resonance (CMR) scanning. B. we intend to use novel invasive coronary physiological measurements to assess the dynamic response of the coronary microvasculature to the hyperoxaemic stimulation. This study will establish the implications of high flow oxygen on coronary microvascular function and may have a direct impact on clinical care and the management of patients presenting with chest pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/YH/1089

Study design
Non-randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Topic: Cardiovascular disease; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions

Administration of high flow oxygen

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Quantificaton of myocardial blood flow; timepoint(s): unspecified

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/09/2014

Completion date
01/09/2015

Eligibility

Key inclusion criteria
Patients:
Known coronary artery disease involving one or more major epicardial vessels (=2.5mm diameter) with severe coronary artery disease (coronary luminal stenosis severity =70% or FFR =0.8).

For the healthy volunteer group:
No known risk factors for underlying coronary artery disease

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 90; UK Sample Size: 90

Key exclusion criteria
1. Clinically unstable
2. Previous coronary artery bypass grafting
3. Contraindication to adenosine (regular adenosine antagonist medication, significant reversible airways disease, second or third degree atrioventricular heart block, sinoatrial disease)
4. Pregnancy or breast feeding
5. Recent acute coronary syndrome (<6 weeks)

6. Nonsinus rhythm
7. Chronic obstructive airways disease with a history of hypercapnic respiratory failure
8. Three vessel coronary artery disease
9. Claustrophobia
10. Known adverse reaction to adenosine or iodinated contrast agents

Date of first enrolment
01/09/2014

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Academic Unit of Cardiovascular Medicine
Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Woodhouse Lane
Leeds
England
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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Research organisation

Funder Name
Heart Research UK; Grant Codes: TRP31/14

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?
Results article	results	01/06/2016		Yes	No
HRA research summary			28/06/2023	No	No