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

Recruitment status	[X] Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	[X] Results
Condition category Circulatory System	[] Individual participant data
	Overall study status Completed Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Quantification 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 United Kingdom LS2 9JT

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