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

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

#### 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

Protocol serial number 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

#### Study type(s)

Treatment

#### 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(s)

Quantification of myocardial blood flow; timepoint(s): unspecified

#### Key secondary outcome(s))

Not provided at time of registration

#### 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

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

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

## Sponsor information

#### Organisation

University of Leeds (UK)

#### **ROR**

https://ror.org/024mrxd33

## Funder(s)

#### Funder type

Research organisation

#### **Funder Name**

Heart Research UK; Grant Codes: TRP31/14

#### Alternative Name(s)

**HRUK** 

#### **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?
Results article	results	01/06/2016		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes