# The role of autonomic responses to cardiopulmonary exercise testing in predicting surgical outcome in non-cardiac surgical patients

Submission date	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>		
19/02/2014		Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/08/2014	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
04/03/2020	Surgery			

#### Plain English summary of protocol

Background and study aims

An important minority of patients develop complications after surgery. These complications can include infections, heart attacks, heart damage and damage to other organs, such as the kidney or brain. It is thought that it may be possible to predict which patients will go on to develop these complications before they undergo surgery. Such knowledge would allow doctors to take steps to reduce the medical risks of surgery. It would also aid the development of future trials of different treatments aimed at reducing said risks. While we are aware of some of the reasons why complications are more likely to happen in some people after surgery, there are a number of potential factors that may increase the risk that are, as yet, not fully understood. Here, we are looking at how the brain controls the heart and immune system after surgery. In healthy people, the brain carefully controls how parts of the nervous system help control inflammation and heart function. After surgery, this control system can change and may contribute to the body not being able to heal or recover as well or as quickly as expected. By measuring nervous system and heart function, we will identify patterns that are linked to patients developing complications that cause problems with their recovery after surgery.

#### Who can participate?

All adult patients aged 18-95 referred for cardiopulmonary exercise testing (an exercise test that examines how the lungs, heart and muscles work) before undergoing major non-cardiac (i.e. not involving the heart) surgery

#### What does the study involve?

As part of the medical assessment process before major surgery, some patients have a cardiopulmonary exercise test. The aim of this test is to see how physically fit the patient is as well as other medical information. This can help doctors develop a treatment plan tailored to the needs of the patient. Each patient is asked to give a blood sample for analysis and their heart rate (ECG) measured before, during and after the exercise test. All patients are monitored throughout their hospital stay. Data about how they recover after surgery and their medical

condition is recorded on days 3, 5, 7 and 14 after surgery. This study is observational, meaning that there are no changes to the medical or surgical treatment of patients involved.

What are the possible benefits and risks of participating? There are no disadvantages/risks of taking part. The information we receive from this study may help us to treat patients who are having surgery in the future.

Where is the study run from? University College London (UK)

When is the study starting and how long is it expected to run for? March 2013 to March 2015

Who is funding the study? Academy of Medical Sciences (UK) Centre for Anaesthesia, Critical Care and Pain Management (UK)

Who is the main contact? Dr Gareth Ackland (See contact details below)

# Contact information

#### Type(s)

Scientific

#### Contact name

Dr Gareth Ackland

#### Contact details

Wolfson Institute for Biomedical Research Gower Street London United Kingdom WC1E 6BT

# Additional identifiers

Protocol serial number 13695

# Study information

#### Scientific Title

The role of autonomic responses to cardiopulmonary exercise testing in predicting surgical outcome in non-cardiac surgical patients: an observational cohort study

#### **Acronym**

POM-HR

#### **Study objectives**

Patients with abnormal heart rate recovery have a prolonged length of stay postoperatively and greater postoperative morbidity.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

12/LO/0453

#### Study design

Non-randomised; Observational; Design type: Cohort study

#### Primary study design

Observational

#### Study type(s)

Diagnostic

#### Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Surgery, Anaesthetics

#### **Interventions**

No interventions, Observational; Follow Up Length: 0 month(s)

#### Intervention Type

Procedure/Surgery

#### Phase

Not Applicable

#### Primary outcome(s)

Post-operative morbidity survey; Timepoint(s): Preop, postop days 3, 7, 14

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

01/03/2015

# **Eligibility**

#### Key inclusion criteria

- 1. All surgical patients referred for cardiopulmonary exercise testing preoperatively undergoing major non-cardiac surgery
- 2. Aged 18-95 years

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Lower age limit

18 years

#### Upper age limit

95 years

#### Sex

All

#### Key exclusion criteria

- 1. History of exercise-induced angioedema
- 2. Pregnancy
- 3. Any contraindication to cardiopulmonary exercise testing (as outlined by American Association of Anaesthesia)

#### Date of first enrolment

01/03/2013

#### Date of final enrolment

01/03/2015

## Locations

#### Countries of recruitment

**United Kingdom** 

England

# Study participating centre Wolfson Institute for Biomedical Research

London United Kingdom WC1E 6BT

# Sponsor information

#### Organisation

University College London Hospitals NHS Foundation Trust & University College London (UK)

#### ROR

https://ror.org/042fqyp44

# Funder(s)

#### Funder type

University/education

#### Funder Name

Academy of Medical Sciences (UK)

#### Alternative Name(s)

The Academy of Medical Sciences

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Universities (academic only)

#### Location

**United Kingdom** 

#### Funder Name

Centre for Anaesthesia, Critical Care and Pain Management (UK)

# **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	01/07/2017	22/01/2019	Yes	No
Results article	results	01/01/2018	22/01/2019	Yes	No
Other publications	secondary analysis	21/08/2019	04/03/2020	Yes	No