

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

Submission date 19/02/2014	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/08/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/03/2020	Condition category Surgery	☐ Individual participant data

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

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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

Primary study design

Observational

Study design

Non-randomised; Observational; Design type: Cohort study

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

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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