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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

Registration date
22/08/2014

Overall study status
Completed

Last Edited
04/03/2020

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Wolfson Institute for Biomedical Research
Gower Street
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

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

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/03/2013

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
95 Years

Sex
Both

Target number of participants
Planned Sample Size: 778; UK Sample Size: 778; Description: Elective non-cardiac surgical patients

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
England

United Kingdom

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)

Sponsor details
Gower Street
London
England
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Sponsor type
University/education

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

Other non-profit organizations

Location
United Kingdom

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

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	01/07/2017	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