

The measurement of heart and circulation parameters performed non-invasively and used as a method to predict outcome for acute medical admission patients

Submission date 19/08/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/09/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/09/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study is looking at whether monitoring cardiac output (the amount of blood being pumped by the heart every minute), oxygen delivery (the amount of oxygen getting to the body tissues) and microcirculatory status (the flow of blood or lymph through the smallest vessels in the body) in acute medical patients (patients admitted to hospital as emergency cases) helps in building up a comprehensive and timely picture of how the patient is doing and whether they are likely to need treatment in intensive care.

Who can participate?

Adults (aged at least 18) admitted as emergency cases and likely to need more than 24 hours of hospital care.

What does the study involve?

All patients undergo both cardiac output and oxygen delivery monitoring, taking into account any supplementary oxygen being provided in the calculations. The state of the tiny vessels making up the microcirculation is assessed using a technique called microvision medical microscan. All data is collected. Urine samples are also taken to test kidney function. This monitoring is done for all eligible participants that have been admitted to the hospital over the preceding 24 hours. All patients are then followed up for the next 30 days to see how well they have recovered.

What are the possible benefits and risks of participating?

The main objective of this study is to see whether taking these additional non-invasive measurements are helpful in identifying unwell patients more effectively and earlier. This may then have an impact on for example the referral of patients to the intensive care unit. There may be a link between these more advanced measures and subsequent course of illness which we would hope to investigate further. If this is the case, it may be important to use this type of monitoring routinely outside the intensive care unit in the future. There is no immediate

personal benefit to someone being involved in the study and the measurements will not be used to change usual medical care in any way, however it is possible that future medical practice could change based on the results of the study. There are small risks associated with taking the described measurements, including some temporary discomfort when applying the cycling inflatable cuff on patients' finger or wrists, small skin tears upon removal of adhesive stickers and damage to the teeth caused by a probe placed under the tongue to measure microcirculation.

Where is the study run from?

Royal Surrey County Hospital NHS Foundation Trust (UK)

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

April 2016 to October 2016

Who is funding the study?

Surrey Peri-Operative Anaesthesia and Critical Care Collaborative Research Group (SPACER)

Who is the main contact?

Dr James Doyle

james.doyle4@nhs.net

Contact information

Type(s)

Scientific

Contact name

Dr James Doyle

ORCID ID

<http://orcid.org/0000-0002-7060-0373>

Contact details

c/o Intensive Care Unit

Royal Surrey County Hospital NHS Foundation Trust

Egerton Rd

Guildford

United Kingdom

GU2 7XX

01483571122

james.doyle4@nhs.net

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

F1

Study information

Scientific Title

Non-invasive Cardiac output, Oxygen delivery and sub-lingual Micro-circulation as a predictive tool in acute MedICAL admission patients

Acronym

COM-MICAL study

Study objectives

By non-invasively monitoring these variables (cardiac output, oxygen delivery and microcirculatory status) in acute medical patients we will build a more comprehensive and timely picture of a patient's physiology. This could subsequently be used as a predictor for outcome or identifier of those patients requiring intensive care management.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Royal Surrey County Hospital Research and Development Department, 27/07/2016

Study design

Feasibility / Pilot Cohort Observational Study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Acute medical patients

Interventions

Cardiac output will be measured via a non-invasive monitor, utilising either bioreactance, pulse wave power analysis or Doppler technologies. Oxygen content and saturations will be measured via a non-invasive finger probe that measures total haemoglobin (SpHb). Details of any supplemental oxygen the patient is receiving will be recorded then with the use of a simple calculation (performed during our data analysis) the blood oxygen delivery can then be

determined. The micro-circulatory status will be measured using microvision medical microscan. This device uses sidestream darkfield (SDF) imaging to build a real-time video image of blood flow within the sublingual microcirculation.

All the above variables would be measured after the initial medical therapy treatment in acute medical patients. As such it has been decided to take the measurements of all patients from the preceding 24 hours medical take. This is preferable to at patient arrival as patients commonly present at different stages of disease progression (i.e. some patients attend ED immediately whilst some attend much later)

The Sequence of Events:

The data collection will take place over an intensive sprint of 7 days.

On each morning all acute medical patients that have been admitted during the preceding 24-hour period will be identified.

On enrolment cardiac output, oxygen content and microcirculatory status measurements will be performed. Subsequently a urine sample will be used to look for markers of AKI, which will be repeated 24 hours later.

Follow up will occur at 30 days.

Intervention Type

Device

Primary outcome measure

30-day mortality

Secondary outcome measures

1. Admission to ICU within 30 days
2. Occurrence of acute kidney injury (AKI) within 30 days
3. Hospital length of stay (within 30 days)

Overall study start date

29/04/2016

Completion date

31/10/2016

Eligibility

Key inclusion criteria

1. Adults patients (aged 18 yrs or over)
2. All patients (expected to require more than 24 hours of hospital based care) admitted under the general medical take to Royal Surrey County Hospital during the study period

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

140

Key exclusion criteria

1. Children (aged 17 or under)
2. Any patient in which consent or NOK assent is unable to be obtained prior to obtaining measurements
3. The absence of intact skin over the cardiac output sample site (e.g. severe burns, or dermatological conditions such as severe blistering conditions)
4. Glossectomy
5. Glossitis
6. Oral ulceration
7. Lack of mental capacity
8. Inability to communicate in the English language

Date of first enrolment

24/09/2016

Date of final enrolment

31/10/2016

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Royal Surrey County Hospital NHS Foundation Trust

Egerton Road

Guildford

United Kingdom

GU2 7XX

Sponsor information**Organisation**

Royal Surrey County Hospital NHS Foundation Trust

Sponsor details

Research and Development Unit
Royal Surrey County Hospital NHS Foundation Trust
Egerton Rd
Guildford
England
United Kingdom
GU2 7XX

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/050bd8661>

Funder(s)**Funder type**

Not defined

Funder Name

Surrey Peri-Operative Anaesthesia and Critical Care Collaborative Research Group (SPACER)

Results and Publications**Publication and dissemination plan**

The results of this study will be published by peer-reviewed journals and presented at international surgical, anaesthetic and perioperative medicine conferences.

Intention to publish date

01/01/2017

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Stored in repository