ISRCTN82077534 https://doi.org/10.1186/ISRCTN82077534

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	**Recruitment status**	[X] Prospectively registered
19/08/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/09/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
02/09/2016	Circulatory System	[_] 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 fir 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 years 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
https://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

Protocol serial number
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

Study type(s)
Screening

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(s)
30-day mortality

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guidford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital NHS Foundation Trust

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository