ISRCTN15439489 https://doi.org/10.1186/ISRCTN15439489

Detecting low brain oxygen levels in patients undergoing non-cardiac surgery to assess its association with post-operative delirium

Submission date
29/08/2018

Recruitment status
No longer recruiting

Registration date
06/11/2018

Overall study status
Completed

Last Edited
22/03/2021

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims (brief description of the disease or area of study, what are the objectives/aim of the study)

The aim is to explore the use of a novel monitor, during general anaesthesia and surgery, that non-invasively measures the levels of oxygen in the brain. We will also look for the uncommon complication of delirium occurring early in the postoperative period.

Who can participate? (what are the age range and gender of the participants, can they only participate if they have a certain condition or if they are healthy volunteers?)

Specific patients having surgery at this hospital will be approached.

What does the study involve? (what interventions will be compared, will all participants receive the same treatment?)

The use of a new monitor before, during and for one hour after surgery.

What are the possible benefits and risks of participating? (what can participants gain from enrolling, are there any side effects of the treatments and if so, what are the symptoms?)
No potential benefit. Trivial risk of having allergic to the adhesive on the sensor.

Where is the study run from? (what are the approximate number and names of centres taking part in this trial, if there is a lead centre, which one is it?)
Royal Surrey County Hospital NHS Foundation Trust

When is the study starting and how long is it expected to run for? (what is the anticipated start date and the approximate duration of the trial?)
September 2018 to January 2019

Who is funding the study? (who will be paying the costs that the trial will incur during its lifecycle?)
Medtronic, the manufacturer of the sensors and device.

Who is the main contact? (if this is the same as the contact in the record, please provide the name and email address only, if different to the contact in the record, please provide the name, position they hold at the institution/organisation and their email address)
Ben Creagh-Brown, bencb@nhs.net

Contact information

Type(s)
Public

Contact name
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Contact details
Royal Surrey County Hospital
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Additional identifiers

Protocol serial number
1.31

Study information

Scientific Title
Using near-infrared spectroscopy to detect cerebral desaturation in non-cardiac surgery and assess its relationship with post-operative delirium– a pilot study

Acronym
CereOx

Study objectives
Low baseline cerebral oximetry values, or some metric of peri-operative cerebral desaturation may be more closely associated with post-operative delirium than other variables including systemic blood pressure.

Ethics approval required
Old ethics approval format

Ethics approval(s)

London - Bloomsbury Research Ethics Committee reviewed the above application on 21 June 2018. REC reference: 18/LO/1122

Primary study design
Observational

Study design
Prospective observational cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Postoperative delirium

Interventions
Measurement of cerebral oximetry, from entering the anaesthetic room to 1 hour after the end of surgery

Intervention Type
Device

Primary outcome(s)
The following will be assessed once the final participant has finished the study (as these measurements require the total number of patients):
1. Proportion of patients enrolled in whom we acquired interpretable regional oxygen saturation (rScO2) data (%) is assessed: 100 X total number recruited with interpretable data / total number recruited
2. Proportion of patients enrolled in whom we acquired delirium data (%) is assessed: 100 X total number recruited with delirium data / total number recruited

Key secondary outcome(s)
For each cohort of surgical patients, and the cohort as a whole, use descriptive statistics (proportion (%), or mean and standard deviation, or median and interquartile range – according to parametric or non-parametric distribution respectively):
1. Incidence of cerebral desaturation using three previously utilised definitions (as below). Cerebral saturation is assessed using a cerebral oximetry machine, recorded continuously during surgery and for 1 hour after surgery.
1.1. Any occurrence of a decrease of 10% from baseline
1.2. Any occurrence of a decrease of 20% from baseline
1.3. Any occurrence of an absolute value of regional oxygen saturation (rScO2) <50%
2. Average duration of relative desaturation - time with rScO2 ≤ 60%
3. Incidence of systemic hypotension using three common definitions (as below). Systolic hypotension is assessed using blood pressure readings taken during surgery. Baseline values will be obtained from the pre-operative clinic; however, if this is not possible then the pre-induction blood pressure will be used as a baseline.
3.1. Any occurrence of systolic blood pressure (BP) ≤20% of baseline
3.2. Any occurrence of systolic BP ≤30% of baseline
3.3. Any occurrence of systolic BP ≤40% of baseline
4. Average duration of systemic hypotension - time with mean arterial pressure (MAP) ≤20% of baseline

5. Incidence of hypoxaemia using three definitions (as below). Hypoxaemia will be assessed using saturation probe readings during surgery.
5.1. Any occurrence of blood oxygen saturation (SpO_2) ≤ 88%
5.2. Any occurrence of SpO_2 ≤ 90%
5.3. Any occurrence of SpO_2 ≤ 92%
6. Average duration of hypoxaemia - time with SpO_2 ≤ 90%
7. Utilisation of vasopressor drugs (α-agonists) - we will record either a vasopressor infusion or bolus is given during surgery, and if any are given during the recovery. Time administered, drug, dose and the Mean Arterial Pressure (obtained from the anaesthetic machine) will be recorded by the clinician
8. Baseline $rScO_2$ values
9. The incidence of delirium during the postoperative in-patient stay (up to day 7), assessed using 4AT (clinic test for delirium)
10. For the cohort as a whole, compare the difference in variables listed above (1 to 8) between those who developed postoperative delirium and those who did not, using appropriate statistical test: Chi-squared for proportions, unpaired test-t for continuous parametrically-distributed variables, Mann-Whitney U test for continuous non-parametrically-distributed variables.

Completion date
01/02/2019

Eligibility

Key inclusion criteria
Patients:
1. Age ≥ 60
2. Able to provide informed consent

Surgical types:
1. Scheduled orthopaedic surgery (GA/sedation +/- regional)
2. Scheduled gastrointestinal surgery (open/closed)
3. Scheduled robotic urological or gynaecological surgery
4. Emergency laparotomy surgery

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
60

Key exclusion criteria

1. Acute or chronic cognitive impairment, including delirium or dementia
2. Previous neurosurgery
3. Insufficient English language to discuss participation

Date of first enrolment
03/09/2018

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Surrey County Hospital
Egerton Road
Guildford
United Kingdom
GU2 7XX

Sponsor information

Organisation
Royal Surrey County Hospital

ROR
https://ror.org/02w7x5c08

Funder(s)

Funder type
Industry

Funder Name
Medtronic

Alternative Name(s)
Medtronic Inc.

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/06/2021	22/03/2021	Yes	No
HRA research summary			28/06/2023	No	No