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The AUTOFLOW Study - using data to predict if oxygen levels in the brain and kidneys are likely to become low.

Submission date
22/02/2022

Recruitment status
No longer recruiting

Registration date
16/06/2022

Overall study status
Completed

Last Edited
16/06/2022

Condition category
Surgery

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The body uses oxygen to release energy to fuel itself. The brain and kidneys have a high oxygen requirement and consume about a fifth of the body's supply from the blood. When changes in blood flow occur, for example during surgery, the brain and kidneys are at risk of injury due to lack of oxygen.

To protect these organs, there is a process that maintains a more or less constant blood flow to them called autoregulation. It only works when blood pressure is between certain upper and lower limits. Outside of these protective limits, blood flow will fluctuate, and injury may occur.

Our primary aim is to collect data from the brain and kidneys about blood pressure and oxygen levels, and to relate the measurements. This will help us to develop an algorithm to predict if oxygen levels in the brain and kidneys are likely to become low. If clinicians get prior warning of these events, then they can potentially treat and avoid low oxygen levels, safeguarding the brain and kidneys.

Our secondary aim is compare and contrast the predictive algorithms informed by invasive and by non-invasive blood pressure measurements.

Who can participate?
People over the age of 18 years having non-cardiac surgery that is expected to last at least 90 minutes.

What does the study involve?
To the monitoring necessary for routine care in theatre, we will add some sensors that emit a special type of light to look at tissue oxygen levels in the brain, kidney and quadriceps muscle of the participants. We will also add a finger cuff that measures their blood pressure in a different way to normal. We will collect data from all of these devices for the duration of their surgery only. There are no follow-up visits for the participant.

What are the potential benefits and risks of participating?
There is no potential benefit for participants and the only potential harm is the small possibility of burns from the sensors or pressure injuries from the finger cuff.

Where is the study run from?
York & Scarborough Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting & how long is it expected to run for?
September 2020 to April 2023

Who is funding the study?
Edwards Lifesciences, California (USA)

Who is the main contact?
Dr Simon Davies, simon.davies@york.nhs.uk

Contact information

Type(s)
Principal Investigator

Contact name
Dr Simon Davies

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290456

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 290456, CPMS 47669

Study information

Scientific Title
Development of algorithms for the prediction of the limits of autoregulation for cerebral and renal blood flow during major surgery with continuous invasive and non-invasive blood pressure measurements.

Acronym
AUTOFLOW

Study objectives
1. The first objective is to develop an algorithm based on cerebral and renal oxygenation values and invasive blood pressure measurements;
2. The second objective is to develop an algorithm based on cerebral and renal oxygenation values and non-invasive blood pressure measurements;
3. The third objective is to assess the agreement between these two methods.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/11/2020, Office for Research Ethics Committees Northern Ireland (ORECNI Office, Lissue Industrial Estate West, Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 2895 361 400; RECB@hscni.net), ref: 20/NI/0166

Study design
Multicentre prospective observational study

Primary study design
Observational

Secondary study design
Basic science study involving procedures with human participants

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Prevention of cerebral and renal desaturation in major non-cardiac surgery.

Interventions
Prior to anaesthetic induction, participants will receive routine invasive haemodynamic monitoring via an arterial line (FloTrac sensor). Additionally, a finger cuff (ClearSight) will be applied to the middle finger of the ipsilateral hand for non-invasive haemodynamic monitoring.

Four NIRS sensors (ForeSight) will be applied – two to the forehead for cerebral oxygenation, one to the right flank for renal oxygenation, and one to the quadriceps for peripheral oxygenation. All monitoring tools will be connected to Hemosphere monitors.

The rest of the procedure will be performed according to routine clinical practice and no study-related interventions will be made. All interventions made during the procedure, including - but not limited to - fluid therapy, vasoactive drug administration and positional changes, will be entered on to the Hemosphere. None of the sensors will be used to guide treatment, except for the FloTrac, which will be used according to routine clinical practice.

When the procedure is finished, data collection will be stopped, and all sensors will be removed after the participant is extubated on the operating table or before the participant is transported to their hospital bed. Participation in the study will end at this point.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
ClearSight finger cuff, ForeSight NIRS sensor

Primary outcome measure
Raw waveform data collected using:
1. Haemodynamic monitoring measured using arterial line (FloTrac sensor)
2. Non-invasive haemodynamic monitoring using finger cuff (ClearSight)
3. Four NIRS sensors (ForeSight) two to the forehead for cerebral oxygenation, one to the right flank for renal oxygenation, and one to the quadriceps for peripheral oxygenation

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
09/09/2020

Completion date
10/04/2023

Eligibility

Key inclusion criteria
Patients due to undergo elective major non-cardiac surgery requiring invasive arterial monitoring (decided at the discretion of the treating clinician) under general anaesthesia, and with an expected duration of greater than 90 minutes.

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
100 participants across two sites, 50 from each.

Key exclusion criteria
1. Subject has skin abnormalities affecting the forehead, flank or skin of the upper leg that would prevent monitoring of tissue oxygenation during the study
2. Patients undergoing cardiac surgery with cardiopulmonary bypass (non-pulsatile blood flow)
3. Age <18 years

Date of first enrolment
17/03/2022

Date of final enrolment
10/04/2023

Locations

Countries of recruitment
England

Netherlands

United Kingdom

Study participating centre
York Teaching Hospital
Wigginton Road
York
United Kingdom
YO31 8HE

Study participating centre
University Medical Centre Groningen
Hanzeplein 1
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Sponsor information

Organisation
York Teaching Hospital NHS Foundation Trust

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York Teaching Hospital
Wigginton Road
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Sponsor type
Hospital/treatment centre

Website
https://www.yorkhospitals.nhs.uk/

ROR
https://ror.org/027e4g787

Funder(s)

Funder type
Industry

Funder Name
Edwards Lifesciences

Alternative Name(s)
Edwards, Edwards Lifesciences Corporation, Edwards Lifesciences Corp., Edwards Lifesciences LLC, ELC

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
10/04/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study are not expected to be made available due to their commercial sensitivity, as per Edwards Lifesciences Ltd's IP.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	18/11/2020	23/02/2022	No	Yes
Protocol file	version 2.0	09/11/2020	23/02/2022	No	No
HRA research summary			28/06/2023	No	No