

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/06/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/06/2022	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

290456

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Netherlands

Study participating centre**York Teaching Hospital**

Wigginton Road

York

United Kingdom

YO31 8HE

Study participating centre**University Medical Centre Groningen**

Hanzeplein 1

Groningen

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9713 GZ

Sponsor information

Organisation

York Teaching Hospital NHS Foundation Trust

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, E, ELC

Funding Body Type

Government organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

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?
HRA research summary			28/06/2023	No	No
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