

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

<b>Submission date</b> 22/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/06/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 16/06/2022	<b>Condition category</b> 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](mailto:simon.davies@york.nhs.uk)

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Simon Davies

### Contact details

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## Additional identifiers

Integrated Research Application System (IRAS)

290456

Central Portfolio Management System (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

Netherlands

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?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 3.0	18/11/2020	23/02/2022	No	Yes
<a href="#">Protocol file</a>	version 2.0	09/11/2020	23/02/2022	No	No