

# Intraoperative hypotension in elder patients (IHypE)

<b>Submission date</b> 02/05/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/05/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/11/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Low blood pressure during surgery (also known as intraoperative hypotension or IOH) is thought to be very common. It happens as a side effect of the medicines used during anaesthesia (sedation during surgery). In patients aged over 65 years, this may lead to an increased risk heart attack, stroke, kidney failure and death following surgery. This risk increases as the degree and duration of low blood pressure increases. Patients aged over 65 years are at increased risk because their body is less able to cope with low blood pressure. Finding out how common IOH is can be difficult, as there is no clear and universally accepted definition. The purpose of this study is twofold. Firstly to determine how often low blood pressure occurs during operations in elderly patients in the UK and whether this is linked to a higher risk of complications. Secondly, to determine how and why anaesthetists treat low blood pressure during operations.

### Who can participate?

Patients aged 65 years or older and having surgery under anaesthesia

### What does the study involve?

Taking part in this study does not change the care patients would receive if they were not taking part. The researchers review the anaesthetic charts of participants undergoing surgery and record instances of IOH, as well as how serious it is and how long it lasts. Other key medical and background information is also recorded for each patient. Patients included in the study are followed up to assess their recovery up to 30 days after surgery. All information is obtained from patient records rather than face-to-face encounters. Anaesthetists, who looked after a participant, are given a questionnaire asking about individual practice in relation to the treatment of low blood pressure during surgery. The responses are collected and assessed to determine national consensus on this topic.

### What are the possible benefits and risks of participating?

There are no notable benefits or risks involved with participating.

### Where is the study run from?

University College Hospital and 200 of NHS hospitals (UK)

When is the study starting and how long is it expected to run for?  
June 2015 to June 2017

Who is funding the study?  
National Institute of Academic Anaesthesia (UK)

Who is the main contact?  
Dr Alex Wickham  
alex.wickham@nhs.net

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
31771

## Study information

**Scientific Title**  
Intraoperative Hypotension in Elder Patients (IHypE): an observational study of intraoperative hypotension in patients aged over 65 in UK hospitals

**Acronym**  
IHypE

**Study objectives**  
The aim of this study is to determine how often low blood pressure occurs during operations in elderly patients in the UK and whether this is linked to a higher risk of complications, and to investigate how and why anaesthetists treat low blood pressure during operations.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

## **Study design**

Observational; Design type: Cohort study

## **Primary study design**

Observational

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Specialty: Anaesthesia, perioperative medicine and pain management, Primary sub-specialty: Anaesthesia, Perioperative Medicine and Pain Management; UKCRC code/ Disease: Other/ General symptoms and signs

## **Interventions**

Patient Participants: No direct intervention is made as part of the study. Patient anaesthetic records are examined and data on pre-morbid health state and intraoperative blood pressure is collected. 30 day outcome data (mortality, troponin, creatinine and ischaemic stroke).

Anaesthetist participants: Anaesthetists who have anaesthetised a patient who meets the inclusion criteria will be asked to complete a short survey assessing their opinions on intraoperative hypotension in patients aged over 65 years.

## **Intervention Type**

Other

## **Primary outcome(s)**

Proportion of elderly patients developing intraoperative hypotension (IOH), the percentage drop from baseline blood pressure and the duration of hypotension. IOH will be recorded from reviewing the patients anaesthetic chart within 24 hours of having surgery. Percentage drop from baseline will be calculated using baselines of pre-induction and pre-operative blood pressure and the lowest recorded value. Duration of IOH will be calculated as the time in minutes spent consecutively at or within 5mmHg of the lowest value recorded on the anaesthetic chart.

## **Key secondary outcome(s)**

1. In hospital mortality at 30 days: assessed by review of the clinical record
2. Acute kidney injury within 7 days of surgery: defined as a postoperative creatinine increase  $\geq 1.5$  times the baseline value or  $\geq 26.5 \mu\text{mol/L}$ . Assessed by review of the clinical record
3. Myocardial injury: Defined as a postoperative troponin enzyme concentration within 7 days of surgery that is above the 99th percentile of the upper reference limit. Assessed by review of the clinical record
4. Stroke, defined as an ischaemic stroke reported from a computed tomography (CT) scan of the brain within 7 days of surgery. Assessed by review of the clinical record
5. Anaesthetist perceptions of and treatment thresholds for hypotension is determined by assessment of a questionnaire administered on the date of participant recruitment

## **Completion date**

01/06/2017

# Eligibility

## Key inclusion criteria

1. Aged >65 years
2. Underwent general anaesthesia or regional anaesthesia either alone or in combination in an operating theatre
3. Emergency and elective surgery

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## Key exclusion criteria

1. Procedure requires cardiopulmonary bypass
2. The patient undergoes sedation alone (that is, not in combination with regional anaesthesia)

## Date of first enrolment

21/11/2016

## Date of final enrolment

31/01/2017

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

### University College Hospital

University College London Hospitals NHS Foundation Trust

Euston Road

London

United Kingdom

NW1 2PG

# Sponsor information

## Organisation

University College London

## ROR

<https://ror.org/02jx3x895>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute of Academic Anaesthesia

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because the participants did not provide consent to disseminate participant level data.

### 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 V2.2	07/08/2016	11/05/2017	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes