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Intraoperative hypotension in elder patients (IHypE)

Submission date
02/05/2017

Recruitment status
No longer recruiting

Registration date
02/05/2017

Overall study status
Completed

Last Edited
26/11/2019

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Study website
www.i-hype.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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)
West London & GTAC Research Ethics Committee, 09/08/2016, ref: 16/LO/1154

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

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 measure
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.

Secondary outcome measures
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 ≥1.5 times the baseline value or ≥26.5µmol/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

Overall study start date
01/06/2015

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

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 1700; UK Sample Size: 300

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
England

United Kingdom

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

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name

Results and Publications

Publication and dissemination plan

1. Planned presentation of selected abstracts from the study data at the British Journal of Anaesthesia/ Anaesthetic Research Society 2017 Spring meeting (London), Euroanaesthesia 2017 (Geneva) and the ANZCA ASM 2017 (Brisbane)
2. Planned publication in a high impact peer reviewed Anaesthetic journal by December 2017

Intention to publish date

31/12/2017

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?
Participant information sheet	version V2.2	07/08/2016	11/05/2017	No	Yes
HRA research summary			28/06/2023	No	No