14th July 2016

Study title:	**Intraoperative Hypotension in Elder Patients (IHypE): An Observational Study of Intraoperative Hypotension in patients aged over 65 in UK Hospitals**
REC reference:	**16/LO/1154**
Protocol number:	**15/0970**
IRAS project ID:	**186097**

Dear Dr Lund and the West London & GTAC Research Ethics Committee Members,

We would like to thank you for reviewing our study proposal and the suggestions you have made for improvement/ clarification. We have responded to your points item by item as below:

1) Clarify the aim of the study.

The primary objective is to describe how far blood pressure drops during surgery in UK Anaesthetic practice.

There are several secondary objectives:

i) To determine the blood pressure treatment threshold
ii) To identify anaesthetists opinion about applied treatment thresholds.

2) Clarify the number of intended participants.

Sorry for the confusion. We did not update the documents in their entirety following further centres being included. The study intends to take a snapshot of practice across the UK and the number is derived from the estimated recruitment (based on a previous audit performed in London). We estimate this number to be approximately 2000.

3) Explain why the hospital number in the data collection form is necessary or remove this.

We would like to identify changes in blood tests indicating kidney function or a heart attack – if these have been taken as part of routine care postoperatively. An alternative is to use a code based on operation list order as a pseudoanonymisation key, we would be happy to do this if this is preferable.

4) Clarify if safety concerns could be identified during the study and if you would disseminate such information.

Low blood pressure is a common occurrence during anaesthesia and as such it is unlikely that any blood pressure drop could be considered a safety concern. The aim of the study is to describe blood pressure management in the UK and hopefully reach some further consensus regarding its definition. The study will not specifically aim to compare individual centres with respect to safety. The RAFT network is established with a central committee and consultant representatives in each hospital – any adverse events during the study will be discussed centrally and dealt with using regional governance procedures.

5) Clarify if there would be any potential conflict of interest with trainees collecting data on the practice of senior anaesthetists they are accountable to and how you might mitigate this.

It is common for Anaesthetists of all grades to audit and survey each other's practice. There is no widely accepted good or bad management for intraoperative blood pressure so it is highly unlikely to cause any conflict. Each centre has a consultant lead and there is strong engagement with the consultant body. Any unlikely emerging issues should be easily tackled via the consultant members.

6) Reassure the Sub-Committee that only fully anonymised data will be leaving the NHS Trust that treated the participant or submit consent forms for staff and patients.

This is the case and is being made very clear to all local investigators. Only fully anonymous data will leave the NHS trust. We have no use for any identifiable data beyond gender. As a further safety caveat, it is impossible for local investigators entering data to input patient identifiable information into the database as all fields are 'drop-down' boxes, 'select-a-box' or numerical fields without the facility for freetext.

7) Amend the study advert to make the logo much smaller and include more detail as to what the study is.

Thank you for this suggestion. We have amended the poster but also provided an information sheet (attached) which goes into much greater detail.

8) Amend the study sheet for anaesthetists as follows.
   a) Correct the aims of the project.

   Amended (see attached).

   b) Add the names and contact details of the people running the study.

   Amended (see attached)

   c) Refer any complaints to the study co-ordinating team or chief investigator, and not the local investigator.

   Amended (see attached)

   d) The study sheet for anaesthetists should state that outcome data for 30 days post-op is being collected.

   We have done this, however, whilst 30 day outcome data is being collected, it is not (and physically cannot) being linked to the anaesthetist survey data.

Additionally, we attach copies of the updated information for anaesthetsists document, poster and a new patient information leaflet.

We look forward to your response,

Yours sincerely,

Dr Daniel Martin,

Chief Investigator

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