

IHYPE STUDY INFORMATION SHEET FOR PATIENTS



Trial title	Intraoperative Hypotension in the Elder Patients: Observational Study of		
	Intraoperative Hypotension in Patients aged over 65 in UK Hospitals (iHypE)		
Leaflet version	2.2	Protocol number	5.3

This hospital is taking part in an observational research study to investigate blood pressure during surgery in people aged over 65 years old. This leaflet gives information about the study. Please read the following information carefully and ask the contacts below if there is anything that is unclear or if you would like more information.

1. What is the purpose of the study?

Blood pressure falling during an operation is very common, particularly in those aged over 65. Despite this, there is no widely agreed definition on what blood pressure values constitute a 'low' reading and there remains some uncertainty over when to treat it despite the existence of national guidelines. The purpose of this study is to describe the lower limit of blood pressure encountered during surgery in those aged greater than 65 in the UK. It may be possible that managing blood pressure differently in the future might reduce strain on different body systems, including the kidneys, heart and brain.

2. What does taking part in this study involve?

This study only involves the analysis of data routinely collected during normal clinical care. No additional treatments, observations or tests are being made. Your anaesthetic record will be analysed by an anaesthetic doctor from your hospital, part of your normal care team. Routine information about your health from your anaesthetic record will be noted including: medicines, method of anaesthesia, operation, blood pressure as well as evidence of strain to the kidneys or heart from the results of routine postoperative blood tests.

3. What if I decide I don't want to be a part of this study?

Taking part in this study is voluntary. You may refuse to participate or withdraw at any time without providing a reason. This will not affect the standard of your current or future healthcare or your legal rights. Please ask to speak to the local lead anaesthetist (details below) if you don't want to take part. Please note that once data has been anonymised and sent to the researchers it will not be possible to identify a specific record to withdraw a participant.

4. What are the possible risks?

Because this study only involves analysis of existing data gathered as part of normal clinical care with no changes being made to your treatment, any specific clinical risk is unlikely.

5. What are the possible benefits?

It is unlikely that this study will benefit you directly. However, the knowledge gained from this research may help to improve the quality of anaesthetic care for people having surgery in the future.

6. What do I do if I wish to make a complaint or there is a problem?

If you wish to complain, or have any concerns about any aspect of the way in which you have been approached or treated by members of staff due to participation in the research, the National Health PATLENT INFORMATION SHEET Version 2.2 07/08/2016 IRAS 186097 IH Y PE STUDY INFORMATION SHEET FOR PATIENTS

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Service or University College London (UCL) complaints mechanisms are available to you. Please ask the contacts below if you would like more information on this.

7. Will all information collected about me be kept private?

Data will be collected by the doctors treating you and stored securely within the hospital. Fully anonymised data will be used for analysis. The data will be analysed by Dr Dan Martin, Dr Alex Wickham and Dr David Highton based at University College London Hospitals NHS Foundation Trust.

8. Who is organising the study?

The study is being organised by anaesthetists from the Research and Audit Federation of Trainees (RAFT; <u>www.raftrainees.com</u>), a group of trainee anaesthetists interested in research. The trainees are supported by research anaesthetists from across the UK. The project is sponsored by University College London Hospitals NHS Foundation Trust. Over 150 hospitals across England, Scotland, Wales and Northern Ireland are taking part.

9. Where can I get more information?

Local lead anaesthetist:	Website: <u>www.i-hype.org</u>	
Local Principal Investigator contact:	E-mail:	
	Tel:	
Chief Investigator: Dr Daniel Martin	E-mail: info@i-hype.org	