

# Post-Operative Delirium Investigation in the United Kingdom (PODIUM 1)

<b>Submission date</b> 15/12/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/07/2023	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Over the last ten years there has been an increase in the number of older people having major surgery for a lot of different conditions. Older people are more likely to have problems after surgery and one of the risks is getting delirium. Delirium causes confusion and can sometimes make people forgetful and paranoid. Common problems after surgery like pneumonia and heart attacks are well known but delirium is not as well understood. We know other things will make delirium more likely such as already having dementia or drinking too much alcohol but we don't know a lot about what leads to healthy people getting delirium after surgery. People who develop delirium have a slower recovery and are at risk of developing memory and thinking problems later in life. There has been no research done specifically about how to minimise the risk of delirium for people going under anaesthetic and having surgery. The aim of this study is to look at different treatments people receive when having major surgery and what happens to them afterwards to then be able to see what types of treatment are more likely to cause delirium and inform a bigger study in the future.

### Who can participate?

Patients aged 65 and older who are scheduled to undergo a major elective surgery who are able to give consent to join the study.

### What does the study involve?

After surgery, participants are assessed for delirium and undergo a series of questionnaires. Presence of postoperative delirium (POD) is assessed on the first four postoperative days. Pre-existing health data, choice and dose of anaesthetic agents, use of depth of anaesthesia monitoring, regional versus general anaesthesia and post-operative analgesia as well as incidence of POD and overall severity of other post op complications are all recorded.

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

There is no direct benefit by taking part but results from the study will increase our knowledge in this area and could help people undergoing the same treatment in the future. There are no changes to standard treatment and no additional risk to the patient by taking part in the study.

Where is the study run from?

This study is being run by Freeman Hospital (UK) and takes place in hospitals in the UK.

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

January 2017 to June 2018

Who is funding the study?

Association of Anaesthetists of Great Britain and Ireland (UK)

Who is the main contact?

Dr Iain McCullagh

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## Contact information

### Type(s)

Scientific

### Contact name

Dr Iain McCullagh

### Contact details

Freeman Hospital

Freeman Road

High Heaton

Newcastle upon Tyne

United Kingdom

NE7 7DN

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

8333 - protocol version 2, 04/07/2017.

## Study information

### Scientific Title

Modifiable perioperative risk factors for postoperative delirium in older adults undergoing major elective non-cardiac surgery: a feasibility cohort study

### Acronym

PODIUM 1

### Study objectives

What are the specific drug related and perioperative factors: such as use of certain sedatives, choice of anaesthetic technique, use of depth of anaesthesia monitoring, general vs. regional anaesthesia and epidural or opiate based analgesia; that modify the risk of postoperative delirium and could be modified by a perioperative care bundle in a future clinical trial?

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

North East - Newcastle & North Tyneside 2 Research Ethics Committee, 27/07/2017, ref: 17/NE/0183

### **Study design**

Prospective feasibility cohort study (observational) aiming to recruit a total of 96 patients over the age of 65 scheduled to undergo major elective surgery.

### **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**

Delirium

### **Interventions**

Pre-operatively the participants are assessed for delirium and undergo a series of questionnaires. Presence of postoperative delirium (POD) are assessed on the first four postoperative days. Pre-existing health data, choice and dose of anaesthetic agents, use of depth of anaesthesia monitoring, regional versus general anaesthesia and post-operative analgesia as well as incidence of POD and overall severity of other post op complications are all recorded.

### **Intervention Type**

Other

### **Primary outcome measure**

Incidence of postoperative delirium in patients over 65 years of age following major, elective, non-cardiac surgery in the first four days postoperatively. Screening for delirium will be performed using the 4AT. Additional non study delirium assessments, such as the Confusion assessment method in the intensive care unit (CAM-ICU)<sup>25</sup> which may be performed in critical care areas post op, will also be recorded for comparison.

## **Secondary outcome measures**

1. Number of eligible patients, recruitment rates and retention rates throughout the study.
2. Time required for data collection, preoperative and daily postoperative delirium assessments.
3. To confirm the added value of employing the regional trainee research network (INCARNNET) to deliver the study. Specifically, what proportion of patient consent, data collection and post-operative testing is performed by anaesthesia trainees from this group, especially the success of weekend delirium assessment by trainees

## **Overall study start date**

01/01/2017

## **Completion date**

30/06/2018

# **Eligibility**

## **Key inclusion criteria**

1. Patients over 65 years of age scheduled to undergo major elective, non-cardiac, non neurosurgical elective surgery. Surgical severity will be decided by reference to SORT (Surgical Outcome Risk Tool) criteria.
2. Patient who lack capacity to consent will be included as long as they have a personal consultee who is willing to discuss the study and offer assent, ideally this will be a close relative

## **Participant type(s)**

Patient

## **Age group**

Senior

## **Sex**

Both

## **Target number of participants**

96

## **Total final enrolment**

96

## **Key exclusion criteria**

1. Patients who are 64 years of age and under
2. Those who have require urgent or emergency surgery
3. Those undergoing cardiac and neurosurgery
4. Those unable to provide written informed consent
5. Those unable to understand written English if a translator is not available as part of routine care at the time of recruitment
6. Potential participants that do not have a personal consultee will not be included in the study

## **Date of first enrolment**

01/10/2017

**Date of final enrolment**

05/03/2018

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****The Freeman Hospital**

United Kingdom

NE7 7DN

**Study participating centre****The Royal Victoria Infirmary**

United Kingdom

NE1 4LP

**Study participating centre****Sunderland Royal Hospital**

United Kingdom

SR4 7TP

**Study participating centre****Wansbeck General Hospital**

United Kingdom

NE63 9JJ

**Study participating centre****James Cook University Hospital**

United Kingdom

TS4 3BW

**Sponsor information**

**Organisation**

The Newcastle upon Tyne Hospitals Foundation Trust

**Sponsor details**

The Freeman Hospital  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
England  
United Kingdom  
NE7 7DN

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/05p40t847>

**Funder(s)****Funder type**

Government

**Funder Name**

Association of Anaesthetists of Great Britain and Ireland

**Alternative Name(s)**

Association of Anaesthetists of Great Britain and Ireland, The Association of Anaesthetists, AAGBI

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

**Results and Publications****Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal. See attached protocol.

**Intention to publish date**

31/10/2020

### Individual participant data (IPD) sharing plan

The researchers will not be sharing individual-level data as their patient information sheets /ethics agreement pre-date the June 2017 ICMJE statement and therefore consent for this aspect was not requested.

### 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="#">Results article</a>		15/07/2023	17/07/2023	Yes	No