ISRCTN94663125 https://doi.org/10.1186/ISRCTN94663125

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

Submission date	Recruitment status	[ ] Prospectively registered
15/12/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
17/07/2023	Mental and Behavioural Disorders	

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
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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)25 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?
HRA research summary			28/06/2023	No	No
Results article		15/07/2023	17/07/2023	Yes	No