

A prospective, randomised, controlled evaluation of the effects of optimisation of cerebral oxygenation and depth of anaesthesia on postoperative cognitive functioning in older patients undergoing major orthopaedic and abdominal surgery

Submission date 10/07/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 15/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/09/2012	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
09/07/06 v.1

Study information

Scientific Title

Acronym

PROCEED

Study objectives

Post-operative cognitive decline (POCD) refers to the adverse neurological and neurocognitive changes that many individuals experience after surgery. The types of central nervous system impairments that are characteristic for POCD are short-term or long-term memory and attentional dysfunctions, disturbances in executive functioning and receptive language impairments.

The hypothesis of this trial is that twelve months post-operatively, overall cognitive performance and function on every day activities will be significantly more impaired in post-operative patients than in age matched controls

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Kings College Hospital Research Ethics Committee on the 10th October 2006 (ref: 06/Q0703/168).

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-operative cognitive decline (POCD)

Interventions

1. Bi-spectral index monitor (BIS): monitor of depth of anaesthesia
2. Somanetics invos cerebral oximeter (SICO): monitor of cerebral oxygen saturation

200 out of 250 participants will be patients undergoing surgery all of which will be given the above study interventions.

The remaining 50 participants will form the control group. These individuals will be age-matched control subject who will not undergo surgery. A non-surgical control group is needed in order to monitor the cognitive decline that occurs in this age group independent of surgical interventions

in order to ensure that the potential postoperative cognitive decline is indeed due to the surgical intervention and associated procedures as opposed to naturally occurring age-related cognitive decline.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

1. The Cambridge Assessment for Mental Disorders in the Elderly (section B)

Key secondary outcome(s)

1. The Bristol Activities of Daily Living Scale
2. The Cornell depression scale
3. The Quality of Life instrument (EQ-5D, EuroQolGroup)
4. Cognitive Drug Research Battery (choice reaction time, simple reaction time, digit vigilance reaction time, number vigilance, visual working memory)
5. Client Service Receipt Inventory
6. Confusion Assessment Method
7. Trail-making A and B
8. Stroop Test

Completion date

01/10/2009

Eligibility**Key inclusion criteria**

1. Aged 65 years or over
2. Due to undergo major abdominal or orthopaedic surgery or a healthy relative of such a patient
3. Able to give informed consent
4. Fluency in English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

All

Key exclusion criteria

1. Mild cognitive impairment
2. Dementia

3. Physical disability which would interfere with cognitive interviewing (blindness, inability to write)

Date of first enrolment

01/10/2006

Date of final enrolment

01/10/2009

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

King's College London

London

United Kingdom

SE1 1UL

Sponsor information

Organisation

King's College London (UK)

ROR

<https://ror.org/0220mzb33>

Funder(s)

Funder type

Charity

Funder Name

BUPA Foundation (UK) (Ref. No: NOV05/BALLARD18)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2012		Yes	No