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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 occuring age-related cognitive decline.

Intervention Type
Procedure/Surgery

Phase
Not Specified

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

Secondary outcome measures
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

Overall study start date
01/10/2006

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

Age group
Senior

Sex
Both

Target number of participants
250

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
England

United Kingdom

Study participating centre
King's College London
London
United Kingdom
SE1 1UL

Sponsor information

Organisation
King's College London (UK)

Sponsor details
Guy's Campus
London
England
United Kingdom
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Sponsor type
University/education

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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