ISRCTN36437985 https://doi.org/10.1186/ISRCTN36437985

Surgery Depth of anaesthesia Cognitive outcome (SuDoCo): a pilot study

Submission date 02/03/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/06/2009	**Overall study status** Completed	
Last Edited 24/02/2023	**Condition category** 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
N/A

Study information

Scientific Title
Intra-operative depth of anaesthesia and influence on the incidence of post-operative cognitive deficits: a prospective, randomised, controlled, two-armed single centre pilot trial

Acronym
SuDoCo

Study objectives
Depth of anaesthesia monitored with a bispectral index (BIS) monitor is associated with the incidence of post-operative delirium in patients undergoing general anaesthesia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - Universitätsmedizin Berlin, 22/01/2009, ref: EA1/242/08

Added 04/05/2017:
Secondary POCD-analyses of three trials ('Dexamethasone for Cardiac Surgery (DECS), The Octopus Study: rationale and design of two randomized trials on medical effectiveness, safety, and cost-effectiveness of bypass surgery on the beating heart and SuDoCo) were approved in a separate ethics committee amendment vote of the SuDoCo trial on 26/01/2017 at Charité--Universitätsmedizin Berlin (ref: EA1/242/08). For this secondary analysis, no new data have been collected.

Study design
Prospective randomised controlled two-armed single-centre pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
General anaesthesia

Interventions
In this study two different regimes during general anaesthesia are compared:
1. Unblinded BIS-monitoring (study group)
2. Blinded BIS-monitoring (control group)

Duration of the treatment: during surgery
Follow up: daily for one week until hospital discharge (less than 7 days), 3 months after procedure

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Post-operative delirium incidence (DSM-IV) measuring daily for one week or until hospital discharge (less than 7 days).

Secondary outcome measures
1. Intra-operative bispectral index parameter, measured during surgery
2. Post-operative incidence of delirium (alternative Delirium scores), measured every post-operative day for one week until hospital discharge (less than 7 days)
3. Post-operative incidence of cognitive dysfunction, measured on post-operative day 7 or on day of hospital discharge and day 90
4. Time that discharge criteria were met, measured at discharge from recovery room and discharge from hospital
5. Length of recovery room stay and total hospital stay (LOS)
6. Quality of life measure (EQ-5D), measured on screening day and post-operative day 90
7. Organ dysfunction, measured at hospital discharge
8. Pain, measured in recovery room

Overall study start date
01/03/2009

Completion date
28/02/2012

Eligibility

Key inclusion criteria
1. Written informed consent of the patient
2. Aged greater than or equal to 60 years, either sex
3. Patients undergoing elective general anaesthesia in Charité - Universitätsmedizin Berlin, Campus Virchow-Klinikum with a planned duration of procedure greater than or equal to 1 hour

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
1600

Key exclusion criteria
1. Aged less than 60 years
2. No written consent from the patient
3. Inability to communicate freely in the German language
4. Lacking the willingness to save and hand out pseudonymised data within the clinical study
5. Simultaneous participation of the patient in a pharmaceutical study or having been in a study which was terminated less than a month ago or is planned within a week
6. Accommodation in an institution due to an official or judicial order
7. Members of staff of the Charité
8. History of intra-operative awareness or other reason for unblinded BIS monitoring
9. Mini-Mental Status Examination (MMSE) below 24 or known dementia

Date of first enrolment
16/03/2009

Date of final enrolment
30/08/2010

Locations

Countries of recruitment
Germany

Study participating centre
Charitéplatz 1
Berlin
Germany
10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Charité Universitätsmedizin Berlin

Alternative Name(s)
Medical School - Charité - University Medicine Berlin

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/06/2013		Yes	No

Results article	results	01/03/2015		Yes	No
Other publications	Retrospective data analysis	14/10/2022	01/11/2022	Yes	No
Results article	Secondary analysis	01/02/2023	24/02/2023	Yes	No