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

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

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Prof Claudia Spies

**Contact details**
Charitéplatz 1
Berlin
Germany
10117
+49 (0)30 450 65 10 01
claudia.spies@charite.de

## Additional identifiers

## 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.

## Primary study design
Interventional

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

## Study type(s)
Treatment

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

## Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### 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)

**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

## 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 |
| Results article | Secondary analysis | 01/02/2023 | 24/02/2023 | Yes | No |
| Other publications | Retrospective data analysis | 14/10/2022 | 01/11/2022 | Yes | No |