

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

<b>Submission date</b> 02/03/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/06/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2023	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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

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**

Chariteplatz 1

Berlin

Germany

10117

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c.krukenkamp@charite.de

**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?
<a href="#">Results article</a>	results	01/06/2013		Yes	No

<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Other publications</a>	Retrospective data analysis	14/10/2022	01/11/2022	Yes	No
<a href="#">Results article</a>	Secondary analysis	01/02/2023	24/02/2023	Yes	No