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Peri-operative physostigmine prophylaxis for liver resection patients at risk for delirium and post-operative cognitive dysfunction

Submission date
14/07/2009

Recruitment status
No longer recruiting

Registration date
18/09/2009

Overall study status
Completed

Last Edited
22/05/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Delirium is a syndrome which may present either in a hyperactive form (severe confusion and disorientation) or a hypoactive form (sudden withdrawal from interaction with the outside world). A decline in cognitive function (especially in memory and executive functions) may occur from a few days to several months after surgery – this is known as delirium and postoperative cognitive dysfunction (POCD). POCD occurs quite frequently after major abdominal surgery. The aim of this study is to find out whether giving patients the drug Physostigmine (Anticholium®) reduces the incidence of delirium and POCD.

Who can participate?
Patients aged at least 18 who are undergoing a planned elective liver resection (surgery).

What does the study involve?
A day before liver surgery the participants' cognitive functions are evaluated with the help of paper and pencil tests. Then from the beginning of liver resection participants are randomly allocated to be treated with either Physostigmine or placebo (salt solution) administered into a vein over 24 hours. Blood tests are carried out until the 7th day after surgery. While at the hospital the health condition of the participants is monitored and for the first week after surgery they are visited by the trial team members twice a day. The cognitive tests are repeated on the 7th, 90th and 365th days after surgery.

What are the possible benefits and risks of participating?
By taking part in this study participants will help to expand our knowledge about delirium and POCD and its treatment. The study drugs are routinely used as add-on medications.

Where is the study run from?
The Department of Anesthesiology and Intensive Care CVK/CCM, Campus Virchow Klinikum of the Charité - University Medicine Berlin (Germany)

When is the study starting and how long is it expected to run for?
August 2009 to August 2017

Who is funding the study?
Charité Universitätsmedizin Berlin (Germany)

Who is the main contact?
Prof. Claudia Spies

Contact information

Type(s)
Scientific

Contact name
Prof Claudia Spies

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Additional identifiers

Clinical Trials Information System (CTIS)
2008-007237-47

Protocol serial number
ZS EK 11 618/08

Study information

Scientific Title
Peri-operative physostigmine prophylaxis for liver resection patients at risk for delirium and post-operative cognitive dysfunction: a prospective, randomised, controlled, double-blinded, two-armed single centre trial

Acronym
PHYDELIO

Study objectives
Differences of treatment (Anticholium® versus placebo) in patients undergoing liver resection regarding their mental outcome (delirium and post-operative cognitive deficiency).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Landesamt für Gesundheit und Soziales Berlin (LaGeSo), Germany, 15/01/2009, ref: ZS EK 11 618/08

Study design
Prospective randomised controlled double-blinded two-armed single-centre phase IV trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Delirium, post-operative cognitive dysfunction

Interventions
During liver resection:
1. Peri-operative application of phyostigmine over 24 hours
2. Peri-operative application of placebo over 24 hours

The dosage will be administered intravenously 0.02 mg/kg BW as bolus and 0.01 mg/kg BW/h (for 24 hours) from the beginning of the operation for both intervention arms. The follow up will be 1 year after drug application for all arms.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Anticholium®

Primary outcome(s)
Current primary outcome measures as of 27/06/2016:
1. Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV), measured pre-operatively and up to hospital discharge
2. Cambridge Neurophysiological Test Automated Battery (CANTAB), measured preoperatively, on the 7th, 90th and 365th post-operative day. For the POCD evaluation, a POCD-control group of 25 additionally recruited patients with systemic disease and 20 patients with systemic disease from another non-interventional study (EA1/296/12 Code: Cognitive Outcome after two-stage Liver-Operation)) (ClinicalTrials.gov Identifier: NCT01809782) are analyzed.

Amendment valid from 15/02/2016: The recruitment of a control group regarding the primary endpoint evaluation of POCD was amended. A control group of 45 ASA II/III- patients (20 patients additionally recruited within the Phydelio study and 20 patients from the study (Cognitive Outcome After Two-stage Liver-Operation - NCT01809782)) is additionally collected

for measuring the learning experience during the cognitive testings. The participants are matched on age, education, and gender to the study patients.

Previous primary outcome measures from 04/02/2013 to 27/06/2016 (point 1 was corrected, due to an error in the original application):
1. Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV), measured pre-operatively and up to hospital discharge
2. Cambridge Neurophysiological Test Automated Battery (CANTAB), measured preoperatively, on the 7th, 90th and 365th post-operative day

Previous primary outcome measures until 04/02/2013:
1. Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV), measured pre-operatively and up the the 7th post-operative day
2. Cambridge Neurophysiological Test Automated Battery (CANTAB), measured pre-operatively, on the 7th, 90th and 365th post-operative day

Key secondary outcome(s))

Current secondary outcome measures as of amendment 05 on 07/03/2016:
1. Diagnostics of delirium:
1.1. Confusion Assessment Method (CAM)/Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)
1.2. Intensive Care Delirium Screening Checklist (ICDSC)
1.3. Delirium Detection Scale (DDS)
1.4. Delirium Rating Scale (DRS)
1.5. Nursing Delirium Screening Scale (NuDESC) (already included in the initial application)
2. Evaluation of intensive care unit performance:
2.1. Simplifies Acute Physiology Score (SAPS II)
2.2. Acute Physiological and Chronic Health Evaluation (Apache II)
2.3. Sequental Organ Failure Assessment (SOFA)
2.4. Therapeutic Interventions Scoring System (TISS)
2.5. Richmonds Agitation Sedations Scale (RASS)
2.6. Glasgow Coma Scale (GCS)
2.7. Risk Injury Failure Loss End Stage Kidney Disease (RIFLE)
Added 22/03/2018: Scores of intensive care unit performance will be measured up to ICU discharge but no longer than postoperative day 7
3. Length of post-operative hospital stay, measured by Post-anaesthesia Discharge Scoring Stay (PADSS)
4. Length of post-operative intensive care unit stay according to the criteria of internal standard operating procedures (SOP)
5. Pain:
5.1. Numeric Rating Scale (NRS)
5.2. Verbal Rating Scale (VRS)
5.3. Visual Analogue Scale (VAS)
5.4. Behavioural Pain Scale (BPS)
The secondary outcome parameter "Pain" will be measured pre-operatively and up to hospital discharge
6. The rate of post-operative organ dysfunctions and complications: cerebral-, cardiovascular-, cardiac- pulmonary-, gastrointestinal- and renal dysfunction
Added 22/03/2018: The secondary outcome parameter of postoperative organ dysfunction is measured up to the seventh postoperative day
7. Incidence of systemic inflammatory response syndrome (SIRS) and infection, measured by CDC and American Thoracic Society (ATS) criteria and via laboratory parameters of immunology

Added 22/03/2018: The secondary outcome parameter SIRS and infection will be measured up to the seventh postoperative day.
8. Quality of life questionnaires (questionnaires):
8.1 Quality of life questionnaires 36-item short form health survey (SF-36), EuroQoL instrument (EQ-5D),
8.2. Barthel Index: Activities of Daily Living/Instrumental Activity of Daily Living (ADL/IADL) and Instrumentelle Aktivität im täglichen Leben (IATL)
8.3. Geriatric Depression Scale (GDS), Cornell Depression Scale (CDS), Hospital Anxiety and Depression Scale deutsche Version (HADS-D)
The secondary outcome parameters “Quality of life (questionnaires)” will be measured before the operation, at the day of hospital discharge, 3 months and one year after surgery
9. Mortality, postoperative survival after 90 days, after 6 months and after one year
10. Immune parameters
The secondary outcome parameters "immune parameters" will be measured pre-operatively and up to the seventh post-operative day
11. Parameters of Hematology (Sysmex Europe GmbH)
The secondary outcome parameters "Parameters of Hematology" will be measured pre-operatively and up to hospital discharge
12. Parameters of renal function
The secondary outcome parameters "Parameters of renal function" will be measured pre-operatively and up to the first post-operative day
13. Cortisol level in all study patients from amendment 04, measured at inclusion day, before the operation, first postoperative day and at postoperative day 90
14. Venous return in all study patients from amendment 04, measured intraoperatively
15. Heart rate variability in all study patients from amendment 04, measured intraoperatively
16. Calcification propensity in all study patients from amendment 04, measured on the operation day
17. Transthoracacic echocardiography in all study patients from amendment 04, measured at inclusion day and directly after the operation
18. Frequency of Delirium, Duration of Delirium and Delirium-free days:
18.1. Confusion Assessment Method (CAM)/Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)
18.2. Intensive Care Delirium Screening Checklist (ICDSC)
18.3. Delirium Detection Scale (DDS)
18.4. Delirium Rating Scale (DRS)
18.5 Nursing Delirium Screening Scale (NuDESC)
18.6 Diagnostic and Statistical Manual of Mental Disorders 4th edition (DSM-IV)
19. Frequency of subsyndromal Delirium, subsyndromal Duration of Delirium and subsyndromal Delirium-free days:
19.1 Intensive Care Delirium Screening Checklist (ICDSC)
19.2 Delirium Detection Scale (DDS)
19.3 Nursing Delirium Screening Scale (NuDESC)

Amendment valid from 15/02/2016: The secondary outcome parameters will be measured as above not specified pre-operatively and up to the hospital discharge.

The secondary outcome parameters will be measured as above not specified pre-operatively and up to the seventh post-operative day.

The following secondary outcome measures as of amendment 05 on 07/03/2016 were removed:
11. Perioperative assessment of sleep stage
The secondary outcome parameters "perioperative assessment of sleep stage" will be measured

pre-operatively and up to the first post-operative day
15. Gene expression of clock genes in blood monocytes in 10 study patients, measured perioperatively until the morning of the third postoperative day
16. Light level and light frequency in 10 study patients, measured perioperatively until the morning of the third postoperative day

Secondary outcome measures from 04/02/2013 (points 1 "Diagnostic of Delirium" and 5 "Pain" were corrected, due to an error in the original application) :
1. Diagnostics of Delirium:
1.1. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)
1.2. Intensive Care Delirium Screening Checklist (ICDSC)
1.3. Delirium Detection Scale (DDS)
1.4. Delirium Rating Scale (DRS)
The secondary outcome parameter "Diagnostics of Delirium" will be measured pre-operatively and up to hospital discharge
2. Evaluation of intensive care unit performance:
2.1. Simplifies Acute Physiology Score (SAPS II)
2.2. Acute Physiological and Chronic Health Evaluation (Apache II)
2.3. Sequental Organ Failure Assessment (SOFA)
2.4. Therapeutic Interventions Scoring System (TISS)
2.5. Richmonds Agitation Sedations Scale (RASS)
2.6. Glasgow Coma Scale (GCS)
2.7. Risk Injury Failure Loss End Stage Kidney Disease (RIFLE)
3. Length of post-operative hospital stay, measured by Post-anaesthesia Discharge Scoring Stay (PADSS)
4. Length of post-operative intensive care unit stay according to the criteria of internal standard operating procedures (SOP)
5. Pain:
5.1. Numeric Rating Scale (NRS)
5.2. Verbal Rating Scale (VRS)
5.3. Visual Analogue Scale (VAS)
5.4. Behavioural Pain Scale (BPS)
The secondary outcome parameter "Pain" will be measured pre-operatively and up to hospital discharge
6. The rate of post-operative organ dysfunctions and complications: cerebral-, cardiovascular-, cardiac- pulmonary-, gastrointestinal- and renal dysfunction
7. Incidence of systemic inflammatory response syndrome (SIRS) and infection, measured by CDC and American Thoracic Society (ATS) criteria and via laboratory parameters of immunology
8. Quality of life questionnaires (questionnaires):
8.1 Quality of life questionnaires 36-item short form health survey (SF-36), EuroQoL instrument (EQ-5D),
8.2. Barthel Index: Activities of Daily Living/Instrumental Activity of Daily Living (ADL/IADL) and Instrumentelle Aktivität im täglichen Leben (IATL)
8.3. Geriatric Depression Scale (GDS), Cornell Depression Scale (CDS), Hospital Anxiety and Depression Scale deutsche Version (HADS-D)
The secondary outcome parameters Quality of life (questionnaires) will be measured before the operation, at the day of hospital discharge, 3 months and one year after surgery
9. Mortality, post-operative survival after 90 days, after 6 months and after one year
10. Immune parameters
The secondary outcome parameters "immune parameters" will be measured pre-operatively and up to the seventh post-operative day
11. Perioperative assessment of sleep stage

The secondary outcome parameters "perioperative assessment of sleep stage" will be measured pre-operatively and up to the first post-operative day
12. Parameters of Hematology (Sysmex Europe GmbH)
The secondary outcome parameters "Parameters of Hematology" will be measured pre-operatively and up to hospital discharge
13. Parameters of renal function
The secondary outcome parameters "Parameters of renal function" will be measured pre-operatively and up to the first post-operative day
The secondary outcome parameters will be measured as above not specified pre-operatively and up the the seventh post-operative day.

Additional secondary outcome measures as of amendment 04 on 07/01/2015:
14. Cortisol level in 60 study patients, measured at inclusion day, before the operation, first postoperative day and at postoperative day 90
15. Gene expression of clock genes in blood monocytes in 10 study patients, measured perioperatively until the morning of the third postoperative day
16. Light level and light frequency in 10 study patients, measured perioperatively until the morning of the third postoperative day
17. Venous return in 60 study patients, measured intraoperatively
18. Heart rate variability in 60 study patients, measured intraoperatively
19. Calcification propensity in 60 study patients, measured on the operation day
20. Transthoracacic echocardiography in 60 study patients, measured at inclusion day and directly after the operation

Previous secondary outcome measures until 04/02/2013:
1. Diagnostics of Delirium:
1.1. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)
1.2. Intensive Care Delirium Screening Checklist (ICDSC)
1.3. Delirium Detection Scale (DDS)
1.4. Delirium Rating Scale (DRS)
2. Evaluation of intensive care unit performance:
2.1. Simplifies Acute Physiology Score (SAPS II)
2.2. Acute Physiological and Chronic Health Evaluation (Apache II)
2.3. Sequental Organ Failure Assessment (SOFA)
2.4. Therapeutic Interventions Scoring System (TISS)
2.5. Richmonds Agitation Sedations Scale (RASS)
2.6. Glasgow Coma Scale (GCS)
2.7. Risk Injury Failure Loss End Stage Kidney Disease (RIFLE)
3. Length of post-operative hospital stay, measured by Post-anaesthesia Discharge Scoring Stay (PADSS)
4. Length of post-operative intensive care unit stay according to the criteria of internal standard operating procedures (SOP)
5. Pain:
5.1. Numeric Rating Scale (NRS)
5.2. Verbal Rating Scale (VRS)
5.3. Visual Analogue Scale (VAS)
5.4. Behavioural Pain Scale (BPS)
6. The rate of post-operative organ dysfunctions and complications: cerebral-, cardiovascular-, cardiac- pulmonary-, gastrointestinal- and renal dysfunction
7. Incidence of systemic inflammatory response syndrome (SIRS) and infection, measured by CDC and American Thoracic Society (ATS) criteria and via laboratory parameters of immunology
8. Quality of life (questionnaires) before the operation, at the day of hospital:

8.1. Discharge, 3 months and one year after surgery
8.2. 36-item short form health survey (SF-36), EuroQoL instrument (EQ-5D), Barthel Index
8.3. Activities of Daily Living/Instrumental Activity of Daily Living (ADL/IADL) (German: Instrumentelle Aktivität im täglichen Leben) (IATL)
8.4. Geriatric Depression Scale (GDS), Cornell Depression Scale (CDS), Hospital Anxiety and Depression Scale deutsche Version (HADS-D)
9. Mortality, post-operative survival after 90 days, after 6 months and after one year
10. Immune parameters
10.1. The secondary outcome parameters "immune parameters" will be measured as above not specified pre-operatively and up to the seventh post-operative day
11. Perioperative assessment of sleep stage
11.1. The secondary outcome parameters "perioperative assessment of sleep stage" will be measured as above not specified pre-operatively and up to the first post-operative day

Original secondary outcome measures:
1. Diagnostics of Delirium:
1.1. Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)
1.2. Intensive Care Delirium Screening Checklist (ICDSC)
1.3. Delirium Detection Scale (DDS)
1.4. Delirium Rating Scale (DRS)
2. Evaluation of intensive care unit performance:
2.1. Simplifies Acute Physiology Score (SAPS II)
2.2. Acute Physiological and Chronic Health Evaluation (Apache II)
2.3. Sequental Organ Failure Assessment (SOFA)
2.4. Therapeutic Interventions Scoring System (TISS)
2.5. Richmonds Agitation Sedations Scale (RASS)
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3. Length of post-operative hospital stay, measured by Post-anaesthesia Discharge Scoring Stay (PADSS)
4. Length of post-operative intensive care unit stay according to the criteria of internal standard operating procedures (SOP)
5. Pain:
5.1. Numeric Rating Scale (NRS)
5.2. Verbal Rating Scale (VRS)
5.3. Visual Analogue Scale (VAS)
5.4. Behavioural Pain Scale (BPS)
6. The rate of post-operative organ dysfunctions and complications: cerebral-, cardiovascular-, cardiac- pulmonary-, gastrointestinal- and renal dysfunction
7. Incidence of systemic inflammatory response syndrome (SIRS) and infection, measured by CDC and American Thoracic Society (ATS) criteria and via laboratory parameters of immunology
8. Quality of life (questionnaires) before the operation, at the day of hospital:
8.1. Discharge, 3 months and one year after surgery
8.2. 36-item short form health survey (SF-36), EuroQoL instrument (EQ-5D), Barthel Index
8.3. Activities of Daily Living/Instrumental Activity of Daily Living (ADL/IADL) (German: Instrumentelle Aktivität im täglichen Leben) (IATL)
8.4. Geriatric Depression Scale (GDS), Cornell Depression Scale (CDS), Hospital Anxiety and Depression Scale deutsche Version (HADS-D)
9. Mortality, post-operative survival after 90 days, after 6 months and after one year

The secondary outcome parameters will be measured as above not specified pre-operatively and up to the seventh post-operative day.

Completion date
10/08/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/06/2012:
1. Patients of both genders, aged greater than or equal to 18 years
2. Patients undergoing a planned elective liver resection with or without additional elective surgery in the same session at the University Hospital, Campus Virchow-Klinikum of the Charité - University Medicine Berlin
3. Offered patient information and written informed consent
4. No participation in another clinical trial during the trial and one month before inclusion
5. Negative pregnancy testing (beta-human chorionic gonadotrophin [B-HCG])

Added 27/06/2016:
Participant POCD-control group inclusion criteria:
1. Patients with systemic disease of both genders, aged greater than or equal to 18 years
2. ASA II or III patients undergoing no planned elective surgery in the next year
3. No operation in the last half year before study inclusion
4. Offered patient information and written informed consent

Previous inclusion criteria:
1. Patients of both genders, aged greater than or equal to 18 years
2. Patients undergoing a liver resection (hemihepatectomy and trisectorectomy) at the University Hospital, Campus Virchow-Klinikum of the Charité - University Medicine Berlin
3. Offered patient information and written informed consent
4. No participation in another clinical trial during the trial and one month before inclusion
5. Negative pregnancy testing (beta-human chorionic gonadotrophin [B-HCG])

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
261

Key exclusion criteria

Current exclusion criteria as of 19/06/2012:
1. Aged less than 18 years
2. Pregnancy or lactation
3. Lacking willingness to save and hand out pseudonymised data within the clinical study
4. Accommodation in an institution due to an official or judicial order
5. Advanced disease of the oesophagus of nasopharyngeal cavity
6. Illiteracy
7. Unability of German language use
8. Visual and acustical impairment
9. Score on the mini mental state examination (MMSE) at screening of 23 or less
10. American Society of Anaesthesiologists (ASA) Classification greater than IV
11. Wedge resection
12. Ascertained psychiatric disease
13. Intake of psychotropic drugs (including sleeping pills and Benzodiazepine)
14. Acquired immune deficiency syndrome (AIDS) (Centers for Disease Control and Prevention [CDC] - classification "C")
15. Neoadjuvant Chemo- or radiotherapy within the last 28 days
16. Rheumatoid diseases
17. Colitis ulcerosa
18. Vagotomy
19. Symptomatic bradycardia
20. Known prolongation of QTc - interval greater than 456 ms
21. Regular intake of amiodarone or cholinesters
22. Vagus nerve stimulation in epilepsy
23. Bronchial asthma
24. Allergies and sensibility to physostigmine salicylate
25. Operations in the area of the oesophagus or nasopharynx within the last two months
26. Gangrene
27. Dystrophia myotonica
28. Intoxications by irreversibly acting cholinesterase inhibitor, e.g. organophosphate
29. Closed craniocerebral trauma with medical intervention within one year before inclusion of this study
30. Parkinsons disease
31. Positive history of a depolarisation block after application of a depolarising muscle relaxant or rather after basal narcosis with a depolariser
32. Coronary heart disease Canadian Society of Anaesthesiologists criteria (CSC) stadium IV or the presentation of a coronary heart disease that needs intervention
33. Symptomatic obstructions in gastrointestines and efferent urinary tract
34. Symptomatic cardiac arrythmia
35. Staff of Charite University hospital Berlin, Virchow Klinikum
36. Allergies to any ingredient of the electrode fixing material (only for participants of sleep stage assessment)

Added 27/06/2016:
Participant POCD-control group exclusion criteria:
1. Mini-Mental-State-Examination ≤ 23 Points
2. Missing informed consent for saving and hand out pseudonymous data
3. Neuropsychiatric morbidity, which limits the conduction of the neurocognitive testing
4. Anacusis or hypoacusis, which limits the conduction of the neurocognitive testing
5. Taking psychothropic drugs (including sleep-inducing drug and benzodiazepine) on a regular basis and substances, which limit the conduction of the neurocognitive testing

Previous exclusion criteria:
1. Aged less than 18 years
2. Pregnancy or lactation
3. Lacking willingness to save and hand out pseudonymised data within the clinical study
4. Accommodation in an institution due to an official or judicial order
5. Advanced disease of the oesophagus of nasopharyngeal cavity
6. Illiteracy
7. Unability of German language use
8. Visual and acustical impairment
9. Score on the mini mental state examination (MMSE) at screening of 23 or less
10. American Society of Anaesthesiologists (ASA) Classification greater than IV
11. Start of operation not between 7 a.m. and 1 p.m.
12. Wedge resection
13. Ascertained psychiatric disease
14. Intake of psychotropic drugs (including sleeping pills and Benzodiazepine)
15. Acquired immune deficiency syndrome (AIDS) (Centers for Disease Control and Prevention [CDC] - classification "C")
16. Chemo- or radiotherapy within the last 28 days
17. Rheumatoid diseases
18. Colitis ulcerosa
18. Regular intake of non-steroidal anti-inflammatory drug (NSAID)
19. Vagotomy
20. Symptomatic bradycardia
21. QTc - interval greater than 456 ms
22. Regular intake of amiodarone or cholinesters
23. Vagus nerve stimulation in epilepsy
24. Bronchial asthma
25. Allergies and sensibility to physostigmine salicylate
26. Operations in the area of the oesophagus or nasopharynx within the last two months
27. Gangrene
28. Dystrophia myotonica
29. Intoxications by irreversibly acting cholinesterase inhibitor, e.g. organophosphate
30. Closed craniocerebral trauma with medical intervention within one year before inclusion of this study
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33. Coronary heart disease Canadian Society of Anaesthesiologists criteria (CSC) stadium IV or the presentation of a coronary heart disease that needs intervention
34. Symptomatic obstructions in gastrointestines and efferent urinary tract

Date of first enrolment
01/08/2009

Date of final enrolment
05/09/2016

Locations

Countries of recruitment
Germany

Study participating centre
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin)
Department of Anesthesiology and Intensive Care CVK/CCM
Berlin
Germany
-

Sponsor information

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

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

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

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2021	08/02/2021	Yes	No
Results article	substudy	18/05/2023	22/05/2023	Yes	No