Trial Description

Title

Impact of intraoperative target-controlled EEG sedation monitoring on intraoperative vasopressor support in cardiac surgical patients - an interventional trial

Trial Acronym

NarcoHeart

URL of the trial

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Brief Summary in Lay Language

Anesthesia for surgical procedures is managed by the application of different medications (i.e. sleep medication / hypnotics - pain medication / anagetics - muscle relaxing drugs). Dosage of these drugs is currently based on parmaceutical standards and by the clinical presentation of a patient (for instance heart rate, blood pressure and perspiration). Measurement of narcotic depth is currently not available. Therefore over- or underdosing of narcotics can eventually occur, resulting in possible adverse events for an individual patient. One common side effect of deep anesthesia is blood vessel widening (vasodilation), resulting in low arterial blood pressure. To prevent organ damage (i.e. liver, kidney or brain) drugs (so called catecholamines) or synthetic fluids need to be administered to elevate the blood pressure.
Recently, monitoring of sleep depth based on electro-encephalograhic patterns (EEG) were introduced into the clinical practice (i.e. BIS - bispectral index or Narcotrend). Several clinical trials resulted in advantages for patients saftey, especially in preventing awarness during surgical procedures or in less confusedness after anesthesia. Therefore, the german society of anaesthesiology and intensive care medicine recommend the use of EEG based sleep monitoring not only during anaesthesia for cardiac surgery.

The current clinical trial aims to reduce intraoperative catecholamine and fluid administration during anaesthesia for cardiac surgery by use of EEG based sleep monitoring systems.
Therefore, adults undergoing cardiac surgery by the use of cardiopulmonary bypass (CPB) or bypass grafting without CPB, will be recruited.

Brief Summary in Scientific Language

Based on internal data comig from 330 patients undergoing anaesthesia for cardiac surgery, we demonstrated routinely use of vaopressor support to maintain blood pressure levels above 65 mmHg. Anaesthesia for surgical procedures is managed by the application of different medications (i.e. sleep medication / hypnotics - pain medication / anagetics - muscle relaxing drugs). Dosage of these drugs is currently based on parmaceutical standards and by the clinical presentation of a patient (for instance heart rate, blood pressure and

perspiration). Measurement of narcotic depth is currently not available. Therefore over- or underdosing of narcotics can eventually occur, resulting in possible adverse events for an individual patient. One common side effect of deep anesthesia is blood vessel widening (vasodilation), resulting in low arterial blood pressure. To prevent organ damage (i.e. liver, kidney or brain) drugs (so called catecholamines) or synthetic fluids need to be administered to elevate the blood pressure.
Recently, monitoring of sleep depth based on electro-encephalograhic patterns (EEG) were introduced into the clinical practice (i.e. BIS - bispectral index or Narcotrend). Several clinical trials resulted in advantages for patients saftey, especially in preventing awarness during surgical procedures or in less confusedness after anesthesia. Therefore, the german society of anaesthesiology and intensive care medicine recommend the use of EEG based sleep monitoring not only during anaesthesia for cardiac surgery. Moreover, it was shown recently, that use of EEG based monitoing techniques can reduce intraoperative application of narcotics as well as catecholamins, without increasing the risk for intraoperative awareness.

The current clinical trial aims to reduce intraoperative catecholamine and fluid administration during anaesthesia for cardiac surgery by use of EEG based sleep monitoring systems. The primary endpoint is defined as reduction of intraoperative administration of vasopressor support. Secondary edpoints were focused on (1) intraoperative fluid administration, (2) intraoperative awareness, (3) time to extubation after surgery, (4) rate of postoperative confusedness and (5) raw values between blinded and non-blinded application of EEG processed sleep monitoring.

Do you plan to share individual participant data with other researchers?

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00009232**
- Date of Registration in DRKS: **2015/08/19**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **4468-06/15 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

Secondary IDs

Health condition or Problem studied

- ICD10: **I25.0 - Atherosclerotic cardiovascular disease, so described**
- ICD10: **I08.3 - Combined disorders of mitral, aortic and tricuspid valves**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'>After written informed consent the day before elective cardiac surgery (with or without CPB) patients will be allocated to undergo anaesthesia either by monitoring of EEG processed sleep depth (study arm) or without neuromonitoring (control arm). Sleep depth monitoring will start before induction of anaesthesia and end when transferring the patient to the intensive care unit after surgery. Target range of sleep depth within the study arm, will be aimed between 37 - 64 (Narcotrend states D2-D0) by reducing or increasing narcotic medications. To avoid intraoperative awareness a predefined lowest dosage of narcotics will not come below. In menial sleep depth narcotic medication will be increased. However, as clinical studies mention higher postoperative confusedness in case of very low EEG processed sleep depth values (<20 in BIS; equivalent to stadium F in Narcotrend systems), bolus application of narcotic drugs need to be avoided. In case of hypertension (defined as mean arterial blood pressure > 80 mmHg) in target sleep depth range (stadium D or E), antihypertensive drugs, i.e. Urapidil or Nitrates, should be administered to lower the pressure to 60 - 80 mmHg.</style>
- Arm 2: **Patients allocated to the control arm, will undergo cardiac anaesthesia with EEG processed neuromonitoring blinded to the anaesthetist. Thus, intraoperative patient monitoring will be based on the clinical state of the patient and not by neuromonitoring. However, the blinded EEG data will be evaluated after surgery.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

To evaluate the impact of EEG processed neuromonitoring on intraoperative vasopressor support. Primary endpoint: cumulative intraoperative vasopressor application

To evaluate the impact of EEG processed neuromonitoring on intraoperative vasopressor support. Primary endpoint: cumulative intraoperative vasopressor application

Secondary Outcome

Secondary endpoints focus on (1) intraopoerative fluid administration, (2) intraoperative awareness, (3) time to extubation after surgery, (4) postoperative confusedness and (5) sleep depth between the study arm and control patients

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesiologie und Intensivtherapie, Jena**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/06**
- Target Sample Size: **252**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

-planned and elective cardiac surgery with or without CPB
- Age >18 years
- Written informed consent

Exclusion criteria

- Patient refusal
- Allocation to concurrent interventional trials
- Clinical staff or relatives
- Special operative procedures in hypothermia (i.e. aortic arch operation)
- Conceivable CPB time >3h
- In case of unforeseeable CBP time >3h or massive intraoperative bleeding, patients will be excluded for final study analysis

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/10/28**

Trial Publications, Results and other documents

- Paper **Intraoperative reduction of vasopressors using processed electroencephalographic monitoring in patients undergoing elective cardiac surgery: a randomized clinical trial.**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*