Trial Description

Title

Correlation of subjective pain perception (VAS) and contact heat evoked potentials (CHEP) under remifentanil induced analgesia - with concomitant rating of vigilance by auditory evoked potentials (AEP) and OAA/S-score and analysis of synergistic drug effects on CHEP during propofol-induced loss of consciousness

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Patients' safety during general anesthesia is warranted by numerous monitoring equipment. While the alert patient can express his pain in a detailed manner, pain can only be assessed by indirect parameters as increasing heart rate or blood pressure for the anesthetized patient. These indirect parameters do not change before pain exists. The registration of cerebral electrical activity and its changes by pain (pain evoked potentials) could serve as a method to measure analgesia during general anesthesia. The aim of this study is to design a parameter which detects analgesia objectively and directly during general anesthesia. This would offer an optimum analgesia during general anesthesia. Therefore contact heat will be generated at the skin and pain perception and pain evoked potentials will be recorded, first without drug application and then under analgesic drug. Concomitantly, the state of vigilance will be detected by the reaction of cerebral electrical activity after acoustic stimuli (auditory evoked potentials) and a clinically established score (observer’s assessment of alertness/sedation). Finally, auditory and pain evoked potentials will be recorded under analgesia during loss of consciousness. A correlation between changes of pain perception and changes of pain evoked potentials under analgesia is expected. Potentially sedative drug effects will be detected by auditory evoked potentials. It will be tested if pain evoked potentials serve as an objective and direct parameter of pain reduction even under loss of consciousness and general anesthesia. The study will be conducted before elective general anesthesia in the operating room, healthy patients are required.

Brief Summary in Scientific Language

The basic aim of the study is to investigate the qualification of contact heat evoked potentials (CHEP) as an objective parameter of the analgesic component of general anesthesia. Therefore the analgesic effect of remifentanil after contact heat pain will be assessed via visual analog scale (VAS) and CHEP amplitudes. It has to be shown that CHEP reflect the reduction of pain under remifentanil. The correlation between remifentanil-induced changes of CHEP amplitudes and VAS will affirm the ability of CHEP to reflect analgesic effects objectively, provided that the reduction of pain is caused solely by analgesic effects. Potentially sedative drug effects will be detected by auditory evoked potentials (AEP) and OAA/S-score

(observer's assessment of alertness/sedation). The correlation between CHEP amplitudes and VAS-changes under remifentanil will be compared to a baseline measurement without drug application and for verification of the results four different concentrations of remifentanil will be tested. Furthermore, CHEP will be recorded under loss of consciousness consistent with the conditions of general anesthesia. Therefore, propofol will be applied in addition to the group-specific remifentanil concentration.

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: **DRKS00003300**
- Date of Registration in DRKS: **2011/10/24**
- 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.: **62/2010 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

Health condition or Problem studied

- Free text: **pain during anesthesia**
- ICD10: **R52.9 - Pain, unspecified**

Interventions/Observational Groups

- Arm 1: **measurements without drug application about 30 minutes; after that measurements under 0,05 µg/kg/min remifentanil-infusion (i.v., continuously) about 40 minutes; in the course of the trail additional propofol-infusion until loss of consciousness (defined when volunteers stop squeezing the investigator's hand although requested); occurs shortly after propofol-induction and persists by continuous i.v. propofol-infusion; duration of combined remifentail/propofol-infusion about 30 minutes**
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Arm 2: **measurements without drug application about 30 minutes; after that measurements under 0,10 µg/kg/min remifentanil-infusion (i.v., continuously) about 40 minutes; in the course of the trail additional propofol-infusion until loss of consciousness (defined when volunteers stop squeezing the investigator's hand although requested); occurs shortly after propofol-induction and persists by continuous i.v. propofol-infusion; duration of combined remifentail/propofol-infusion about 30 minutes**

- Arm 3: **measurements without drug application about 30 minutes; after that measurements under 0,20 µg/kg/min remifentanil-infusion (i.v., continuously) about 40 minutes; in the course of the trail additional propofol-infusion until loss of consciousness (defined when volunteers stop squeezing the investigator's hand although requested); occurs shortly after propofol-induction and persists by continuous i.v. propofol-infusion; duration of combined remifentail/propofol-infusion about 30 minutes**
- Arm 4: **measurements without drug application about 30 minutes; after that measurements under 0,40 µg/kg/min remifentanil-infusion (i.v., continuously) about 40 minutes; in the course of the trail additional propofol-infusion until loss of consciousness (defined when volunteers stop squeezing the investigator's hand although requested); occurs shortly after propofol-induction and persists by continuous i.v. propofol-infusion; duration of combined remifentail/propofol-infusion about 30 minutes**

Characteristics

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

Primary Outcome

correlation between individual pain perception (described by visual analogue scale, VAS) and CHEP-amplitudes (Contact Heat Evoked Potentials) as the electroencephalographic correlate of the applied heat pain under remifentanil als analgesic. Remifentanil-induced changes of VAS and CHEP will be compared to the baseline measurement without drug application and will be analyzed under four different remifentanil-concentrations.

Secondary Outcome

- correlation between remifentanil concentration and reduction of CHEP (Contact Heat Evoked Potential)-amplitudes
- registration of potential sedative effects of remifentanil by AEP (auditory evoked

potentials) and OAA/S-score (Observer's Assessment of Alertness/Sedation-score)
- effects of loss of consciousness on CHEP (Contact Heat Evoked Potential)
- gender-related differences on CHEP (Contact Heat Evoked Potential)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/31**
- Target Sample Size: **120**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **50 Years**

Additional Inclusion Criteria

ASA physical status 1-2 (classification system to assess fitness of patients before surgery): correlates with healthy patients (ASA 1) and patients with mild systemic disease (ASA 2), written consent, mental capacity, age: 18-50 years

Exclusion criteria

cardiac, hepatic, renal, pulmonary or gastrointestinal diseases, disorders of gastrointestinal motility, psychiatric and neurologic diseases, altered cerebral perfusion, chronic intake of drugs, psychotropics or other substances with central- or peripheral nervous effects, hypacusis and deafness, analgetic long-term medication, chronic pain, agitated or anxious patients, allergy, known intolerance and contraindications against the used drugs, pregnancy

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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- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Deutsche Forschungsgemeinschaft
Kennedyallee 40
53175 Bonn
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **www.dfg.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*