## Trial Description

### Title

Incidence of dreams and subjective quality of anesthesia during general anesthesia with and without standardised relaxation and dream suggestion by the anesthesiologist

### Trial Acronym

SUGGDREAM

### URL of the trial

[---]*

### Brief Summary in Lay Language

It is known that patients can dream during general anaesthesia. Moreover, it has been shown that a psychologically trained physician can influence the incidence of dreams. Aim of this study is to investigate, whether the incidence of dreaming can be influenced by not psychologically trained anaesthetists and whether the subjective quality of anaesthesia changes by this procedure or not. Participants are adult patients undergoing general anaesthesia. All patients receive the same anaesthetics. The day before anaesthesia the procedure will be explained to the patients. The patients are requested to imagine a dream (dreamfilm) and to communicate the contents to the anaesthetist. Immediately before induction of anaesthesia the anaesthetist performs a standardised procedure for relaxation with the patient and helps the patient to concentrate on his dreamfilm. The anaesthesia will then be performed according to clinical standard procedures. After anaesthesia the patient will be asked for his dreams and subjective quality of anaesthesia. In a control group the incidence of dreaming and subjective quality of anaesthesia without standardised relaxation and suggestion of dreams will be investigated.

### Brief Summary in Scientific Language

It is known that patients can dream during general anaesthesia. Moreover, it has been shown that a psychologically trained physician can influence the incidence of dreams (Gyulahazi). Aim of this prospective non-randomized interventional study is to investigate, whether the incidence of dreaming can be influenced by not psychologically trained anaesthetists and whether the subjective quality of anaesthesia changes by this procedure or not. Participants are adult patients undergoing general anaesthesia usually as total intravenous anaesthesia using propofol, remifentanil and rocuronium. All patients receive the same anaesthetics. The day before anaesthesia the procedure will be explained to the patients. The patients are requested to imagine a dream (dreamfilm) and to communicate the contents to the anaesthetist. Immediately before induction of anaesthesia the anaesthetist performs a standardised procedure for relaxation with the patient and helps the patient to concentrate on his dreamfilm. After anaesthesia the patient will be asked for his dreams and subjective quality of anaesthesia. In a control group the incidence of dreaming and subjective quality of anaesthesia without standardised relaxation and suggestion of dreams will be investigated.
without standardised relaxation and suggestion of dreams will be investigated. If available, measurement of Bispectral Index is planned for all patients to compare depth of anaesthesia between the groups. After informed consent patients are non-randomisedly assigned to a control group and a study group with standardised relaxation and dream suggestion. First the control group will be examined to avoid interaction between group members that might influence the results. A power analysis was performed. For statistical analysis data are tested for normality. The incidence of dreams will compared between Groups using Fisher’s Exact test or Chi-squared test. Subjective Quality of anaesthesia will be investigated using numerical Rating scales and be compared between Groups by T-test or Wilcoxon-test.

References:


Punjasawadwong, Y., A. Phongchiewboon, and N. Bunchungmongkol, Bispectral index for improving anaesthetic delivery and postoperative recovery. The Cochrane Library, 2014.)

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: DRKS00013198
- Date of Registration in DRKS: 2017/11/14
- 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.: D 543/17, Ethikkommission der Christian-Albrechts-Universität zu Kiel

Secondary IDs
### Health condition or Problem studied

- Free text: **Patients undergoing general anaesthesia**

### Interventions/Observational Groups

- **Arm 1:** Control Group undergoing standard general anaesthesia
- **Arm 2:** Standardised Relaxation with breathing and relaxation techniques and Dream Suggestion performed by anaesthetist during induction of anaesthesia

### Characteristics

- **Study Type:** Interventional
- **Study Type Non-Interventional:** [---]*
- **Allocation:** Non-randomized controlled trial
- **Blinding:** [---]*
- **Who is blinded:** [---]*
- **Control:** Control group receives no treatment
- **Purpose:** Treatment
- **Assignment:** Other
- **Phase:** N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels):** N/A

### Primary Outcome

**incidence of dreaming, asked after anaesthesia**

### Secondary Outcome

**subjective Quality of anaesthesia, asked after anaesthesia using numeral Rating scale**

### Countries of recruitment

- DE Germany
Locations of Recruitment

- University Medical Center Klinik für Anästhesiologie und Operative Intensivmedizin, Kiel

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2017/11/22
- Target Sample Size: 80
- 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

Patients undergoing general anaesthesia for oral and maxillofacial surgery

Exclusion criteria

- Missing consent
- Age < 18 years,
- Not able to consent,
- Central nervous system diseases,
- Communication in german not possible
Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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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
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*
- Reason, if Reason for Recruiting Stop "Other": [---]*
- Study Closing (LPLV): 2019/10/15
- Number of Participants in Germany after Recruiting complete: 80
- Total Number of Participants (all Sites worldwide) after Recruiting complete: 80

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.