Trial Description

Title

Effectiveness of Hypnosis with the Dave Elman technique in third molars extraction

Trial Acronym

HypMol

URL of the trial

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Brief Summary in Lay Language

The extraction of third molars is painful for patients. During third molar extractions analgesics are commonly used. However, hypnosis has also shown an analgesic effect and reduced preoperative anxiety, postoperative pain and postoperative consumption of analgesics. However, so far the evidence about the effectiveness of hypnosis in the dental setting is limited since the quality of the studies is in general rather low. The question, if different patients benefit more or less from hypnosis is heavily discussed but not addressed in clinical studies and will be part of this study by investigating patient expectations.

Brief Summary in Scientific Language

The extraction of a third molar is painful for patients and this clinical condition can be used to evaluate analgesic effects of pain treatments. For the reduction of pain during third molar extraction hypnosis can be beneficial. Under hypnosis and during follow up patients show less pain during molar extraction compared to patients without hypnosis. In addition postoperative analgesic use was less in patients with additional hypnosis during third molar extraction. Since the quality of available studies was limited we want to investigate the effectiveness of hypnosis in a within subject study design in order to account for interindividual differences in pain sensitivity.

The aim of this monocentric randomized controlled study is to test the effectiveness of hypnosis in patients with third molar extraction in a within subject design taking into account patients expectations and preferred treatment from the perspective of the patient before having an intervention. A total of 33 patients with molar extractions on both sides will receive two types of pain reducing intervention in order to investigate the effect of hypnosis. During one extraction the patient will first receive hypnosis as add on intervention (Dave Elman technique) and during third molar extraction reduced medication. In the other molar extraction patients will receive regular medication. The order of interventions and side of third molar will be randomized. The primary outcome of the intervention is pain intensity after the extraction (measured 3 hours, in the evening and at the second evening after extraction). Secondary outcomes are pain medication and the preferred treatment after two appointments. Patients will be included if the fulfill the following inclusion criteria. 1) Male and female with third molars in the right and left side of mandibula or maxilla with indication for

extraction. 2) Extractions of third molars are possible in an outpatient dental clinic 3) Age over 16, 4) German language skills to give reliable answers on questionnaires 5) Mobilephone owner. Patients with mental disorders, current use of drugs, or psychotropic / opiod use will be excluded.

Organizational Data

- DRKS-ID: **DRKS00011848**
- Date of Registration in DRKS: **2017/04/11**
- 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.: **BASEC Nr. 2016-02161 , Ethikkommission Ostschweiz (EKOS)**
  Kantonsspital St. Gallen

Secondary IDs

Health condition or Problem studied

- Free text: **Third molar extraction**

Interventions/Observational Groups

- Arm 1: **Extraction of a third molar with additional hypnosis (Dave Elman technique) and reduced anesthetic medication**
- Arm 2: **Extraction of a third molar without hypnosis and regular amount of anesthetic medication**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Active control (effective treament of control group)**

- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Pain intensity AUC (immediately after third molar extraction, 3 h after extraction, evening day 1 after extraction, evening day 2 after extraction; measured with a numeric rating scale (NRS) from 0 to 10)

Secondary Outcome

Postoperative pain medication use (3 h after extraction, evening day 1 after extraction, evening day 2 after extraction; measured with questionnaires), preferred treatment (with or without hypnosis) (before having a molar extraction and after having received both types of treatments; measured with questionnaires)

Countries of recruitment

- CH **Switzerland**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/03/28**
- Target Sample Size: **33**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2017/03/28**

Target Sample Size: **33**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **16 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Patients with third molars in the right and left side with indication for extraction, they need to own a smartphone and they need to have good German language skills

Exclusion criteria

known mental disorder with associated problems for dissociation (schizophrenia, borderline personality disorder, post traumatic stress disorder), current use of illegal drugs, psychotropic drug and opiate use

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 ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethics Approval**

** 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.*