Trial Description

Title

Interactions between chronic orofacial pain, sleep disorder and bruxism (clenching/grinding)

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Many people suffer from stress, insomnia and bruxism. In the long term chronical orofacial pain can develop. The precise relationship between insomnia, teeth grinding and facial pain has been studied very little. Sufficiently well known, however is, that an improved stress management has a positive effect on both sleep quality and pain processing. The aim of this study is to investigate the relationship between teeth grinding, chronic orofacial pain and insomnia as well as to clarify the effectiveness of a stress-reducing treatment regarding MBSR (Mindfulness Based Stress Reduction).

Brief Summary in Scientific Language

As part of an interdisciplinary prospective clinical study sleep parameters will be checked at patients with orofacial pain, bruxism and sleep disorder in order to clarify the question whether a further differentiation within this group of patients is possible. Furtheron it should be examined whether a mindfulness-based therapeutic treatment in a group leads to a change of the parameter "pain" - with the overarching aim to create a differentiated interdisciplinary concept of treatment for this patient group.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003462**
- Date of Registration in DRKS: **2012/01/16**

DRKS-ID: **DRKS00003462**
Date of Registration in DRKS: **2012/01/16**

- 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.: **837.318.11(7860) , Ethik-Kommission bei der Landesärztekammer Rheinland-Pfalz**

Secondary IDs

Health condition or Problem studied

- Free text: **chronic orofacial pain, insomnia, bruxism**
- ICD10: **G47 - Sleep disorders**
- ICD10: **F45.8 - Other somatoform disorders**
- ICD10: **R51 - Headache**

Interventions/Observational Groups

- Arm 1: **MBSR (mindfulness-based stress reduction): The psychotherapeutic intervention takes place in the group, each with 10-15 participants. It will last over eight sessions weekly with 2.5 to 3.5 hours per meeting. Contents will be the instruction in the formal methods of mindfulness (including body scan meditation, Hatah yoga, sitting meditation, walking meditation) and in the informal practice of mindfulness (mindfulness in everyday life). In the 6th week an all-day silent retreat is planned. Participants will receive for the practice of fomal mindfulness a special CD (45 min per day). The informal mindfulness should be practiced six days per week for 5-15 min.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***

Study Type: **Interventional**

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

Allocation: **Single arm study**

Blinding: **Open (masking not used)**

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

- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Main target is the bruxism index, that will be defined pre-and post-intervention by using the "Grindcare" and EMG derivation in the polysomnography.

Secondary Outcome

**Further targets are 1. sleep parameters (subjective based on questionnaires as PSQI/ Munich Parasomnia Screening/ International RLS Study group Rating Scale/Epworth Sleepiness Scale/ Jenkins)
standardized sleep protocol of the German Society for Sleep Medicine and objectively using polysomnography 2. chronic pain: by using individualized pain questionnaire, HADS 3. Salivary cortisol (determination cortisollevels before and after MBSR).**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Mainz und Umgebung**
- University Medical Center **Universitätsmedizin Mainz, Mainz**

Recruitment

- Planned/Actual: **Planned**

Planned/Actual: **Planned**

- (Anticipated or Actual) Date of First Enrollment: **2012/01/16**
- Target Sample Size: **50**
- 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

minimal age of 18 years, patients with at least 3 months of chronic orofacial pain, patients with insomnia, patients with Parafnktionenbruxism, dentition with at least prosthetic rehabilitation on both sides, no presence of occlusal trigger, good compliance, sufficient knowledge of German language,
no analgetic and/or psychotropic medication (or cessation of medication at least three weeks prior study onset)

Exclusion criteria

Age under 18 years, presence of occlusal interferences or triggers, no good compliance,
insufficient german language skills,
abusive alcohol consumption or alcohol dependence, excessive nicotine or other addictive disorders,
patients with sleep-associated breathing disorder, patients with neurological diseases,
patients with serious psychiatric disorders, patients with a complete denture care or no teeth, patients taking centrally acting drugs,co-analgetics and/ or psychotropic medication

Addresses

- **Primary Sponsor**

  Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Poliklinik für Zahnärztliche Chirurgie
  Ms. Univ.-Prof. Dr. Dr. Monika Daubländer
  Augustusplatz 2
  55131 Mainz

Primary Sponsor

Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Poliklinik für Zahnärztliche Chirurgie
Ms. Univ.-Prof. Dr. Dr. Monika Daubländer
Augustusplatz 2
55131 Mainz
Germany

Telephone: **06131-177005**
Fax: **06131-173434**
E-mail: **daublaen at uni-mainz.de**
URL: **www.klinik.uni-mainz.de**

■ **Contact for Scientific Queries**

Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Poliklinik für Zahnärztliche Chirurgie
Ms. Dr. Anastasia Mouratidou
Augustusplatz 2
55131 Mainz
Germany

Telephone: **06131-175090**
Fax: **06131-173434**
E-mail: **anastasia.mouratidou at unimedizin-mainz.de**
URL: **www.klinik.uni-mainz.de**

■ **Contact for Public Queries**

Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Poliklinik für Zahnärztliche Chirurgie
Ms. Dr. Anastasia Mouratidou
Augustusplatz 2
55131 Mainz
Germany

Telephone: **06131-175090**
Fax: **06131-173434**
E-mail: **studie-schlafundschmerz at unimedizin-mainz.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Poliklinik für Zahnärztliche Chirurgie, Minazer Forschungsförderprogramm "MAIFOR"
Ms. Dr. Anastasia Mouratidou
Augustusplatz 2
55131 Mainz
Germany

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

Universitätsmedizin der Johannes Gutenberg-Universität Mainz, Poliklinik für Zahnärztliche Chirurgie, Minazer Forschungsförderprogramm "MAIFOR"
Ms. Dr. Anastasia Mouratidou
Augustusplatz 2
55131 Mainz
Germany

Telephone: **06131-175090**
Fax: **06131-173434**
E-mail: **anastasia.mouratidou at gmx.de**
URL: **www.klinik.uni-mainz.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.*