Trial Description

Title

**How can we treat photophobia in migraine?
A functional imaging investigation of two opposing concepts**

Trial Acronym

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URL of the trial

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Brief Summary in Lay Language

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Brief Summary in Scientific Language

Increased sensitivity to light (photophobia) is a hallmark of migraine which often precipitates headache attacks and handicaps patients by forcing them into a darkened room. Currently it is not known how to treat this stressing symptom and even two directly opposing treatment concepts exist: reduction of light exposure versus desensitisation via controlled exposure. This study will generate the first comprehensive data about the best treatment approach by comparing both strategies directly in the same patients. Besides clinical evaluation, effects of both treatments on subjects brains will be monitored by functional magnetic resonance imaging (fMRI). With such data, a neurophysiologically based recommendation for future effective treatment of photophobia will become possible.

Organizational Data

- DRKS-ID: **DRKS00007739**
- Date of Registration in DRKS: **2015/01/30**
- 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.: **EK-Nr. 1827/2013 , Ethikkommission der Medizinischen Universität Wien**

Secondary IDs

Health condition or Problem studied

- ICD10: **G43.9 - Migraine, unspecified**

Interventions/Observational Groups

- Arm 1: **Light Deprivation Condition:**

  Day 0: baseline fMRI
  Day 1-7: exposition to 1 h complete darkness per day (12.00 – 1.00 p.m.)
  Day 8: postintervention fMRI
- Arm 2: **Light Desensitization Condition:**

  Day 0: baseline fMRI
  Day 1-7: exposition to 1 h flickerlight (5 Hz) per day (12.00 – 1.00 p.m.)
  Day 8: postintervention fMRI

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Basic research/physiological study**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

**a. Difference in mean total (i.e. ictal and interictal) sensitivity to light in the week after
the intervention (days 8 – 14) between light exposure and light deprivation in patients with migraine**

**b. Change in mean total sensitivity to light in the week after light exposure (days 8 –
14) compared to baseline (days -7 – -1) in patients with migraine**

**c. Change in mean total sensitivity to light in the week after light deprivation (days 8
– 14) compared to baseline (days -7 – -1) in patients with migraine**

Secondary Outcome

**a. Differences in mean interictal and mean ictal sensitivity to light in the week after
the intervention (days 8 – 14) between light exposure and light deprivation in patients with migraine**

**b. Changes in mean interictal and mean ictal sensitivity to light in the week after light
exposure (days 8 – 14) compared to baseline (days -7 – -1)**

Countries of recruitment

- AT **Austria**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Neurologie, Wien**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/01**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **70 Years**

Additional Inclusion Criteria

Patients:

**o Migraine without aura according to the criteria of ICHD-III beta
o Migraine present on 1 and 4 days per month in the 3 months preceding study inclusion
o Intensity of interictal sensitivity to light 2 – 6 on a numeric rating scale with range 0-10
o Intensity of ictal sensitivity to light >4 on a numeric rating scale a numeric rating scale with range 0-10**

Controls:

o Matched for age, sex, education and socioecomic status to patients
o No personal or family history of migraine
o sensitivity to light <2 on a numeric rating scale

Exclusion criteria

o Any other recurrent current or previous headache disorder apart from infrequent tension-type headache
o Current or previous medication overuse
o Pregnancy
o Photosensitive epilepsy (excluded by a routine EEG)
o Other current or previous brain disorders
o Ophthalmological disorders relevant to the study
o Psychiatric disorders relevant to the study
o Other diseases relevant to the study including circadian rhythm disorders
o Regular intake of centrally acting compounds including prophylactic medication for
headache in the preceding three months
o Shift and / or night work
o Regular stay in unusually dark or bright environments
o Light therapy within the preceding 3 months
o Strategies to avoid exposure to light within the preceding 3 months
o Claustrophobia
o Metallic implants preventing fMRI
o Current or history of substance abuse
o Any other fMRI contraindications

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

FWF Der Wissenschaftsfonds Haus der Forschung
Sensengasse 1
1090 Wien
Austria

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

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.*