Trial Description

Title

Effects of noisy galvanic vestibular stimulation on walking performance in patients with bilateral vestibulopathy

Trial Acronym

EONGVSOWPIPBV

URL of the trial

[---]*

Brief Summary in Lay Language

Noisy galvanic vestibular stimulation (GVS) has been previously shown to enhance postural balance during standing in healthy subjects and patients with a bilateral vestibular loss. This study examines the effects of noisy GVS on the walking performance in patients with a bilateral vestibular loss.

The walking performance of patients with a bilateral vestibular loss will be recorded during two different conditions at three different walking speeds (slow, preferred, and fast walking): (1) walking with eyes open and zero amplitude noisy GVS (sham stimulation condition) and (2) walking with eyes open and non-zero amplitude noisy GVS set to 80% of the individual sensory threshold for GVS (stimulation condition). The stimulation conditions are tested in a randomized order and subjects are blinded to the stimulation protocol.

We hypothesize that noisy GVS will improve dynamic walking stability in patients with a bilateral vestibular loss. This would offer a future treatment option for walking disturbance in vestibular patients.

Brief Summary in Scientific Language

This study examines the effects of a noisy galvanic vestibular stimulation on the walking performance and postural stability in patients with a bilateral vestibulopathy.

Organizational Data

- DRKS-ID: **DRKS00007875**
- Date of Registration in DRKS: **2015/03/13**
- 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.: **333-07 , Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **H81.8 - Other disorders of vestibular function**

Interventions/Observational Groups

- Arm 1: **Noisy galvanic vestibular stimulation (GVS) set to 80% of the individual sensory threshold of GVS. Stimulation will be given during three two minutes walking trials (slow, preferred, and fast walking). Between trials, participants are given at least two minutes to recover.**
- Arm 2: **Sham noisy galvanic vestibular stimulation (GVS) set to zero Ampere (placebo condition). Sham stimulation will be given during three two minutes walking trials (slow, preferred, and fast walking). Between trials, participants are given at least two minutes to recover.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Placebo**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Changes in spatiotemporal gait parameters derived from treadmill recordings at three different walking speeds (slow, preferred, and fast walking) during stimulation condition and sham stimulation conditions. Each of the total six walking trials will last for two minutes. Ten gait parameters will be analyzed: stride time, stride length, base of support, swing time percentage, double support time percentage as well as gait asymmetry, bilateral phase coordination and the coefficient of variation (CV) of stride time, stride length and base of support.

Secondary Outcome

Changes in the subjective estimation of walking stability: After the recording session, subjects will be asked whether they felt any change in walking stability (improvement or deterioration) between the two stimulation conditions.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Deutsches Schwindel- und Gleichgewichtszentrum, Ludwig-Maximilians-Universität München, München**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/15**
- Target Sample Size: **15**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

Neurologically confirmed bilateral vestibulopathy

Exclusion criteria

auditory, neurological, cardio-vascular or orthopedic disorders

Addresses

- **Primary Sponsor**

  Department of Neurology & German Center for Vertigo and Balance Disorders, Ludwig-Maximilians-University Munich

Primary Sponsor

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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.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/08/30**

Trial Publications, Results and other documents