Trial Description

Title

Prospective investigations of vestibular evoked myogenic potentials (VEMP) in patients with benign paroxysmal positional vertigo (BPPV) in comparison with healthy subjects as a parameter for prognosis an success of therapy

Trial Acronym

VEMP in patients with BPPV

URL of the trial

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Brief Summary in Lay Language

In the study should be investigated if VEMP (vestibular evoked myogenic potentials) could be a parameter of therapy success and a factor for prognosis in patients suffering from BPPV. This contains a comparison of VEMP between patients with BPPV and healthy subjects as well as before and after Dix Halpike or therapeutic manoeuvres.

Brief Summary in Scientific Language

In a prospective, controlled, not randomized study should be investigated if amplitude and latency of VEMP of both sides could be useful as a parameter for prognosis and therapy in patients with BPPV.
Therefore VEMP of 100 patients suffering from BPPV are compared with 100 healthy subjects before and after Dix Hallpike or therapeutic manoeuvres.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00003302**
- Date of Registration in DRKS: **2012/01/20**
- 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**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **EK-BR-73/11-1 , Ethikkommission bei der Sächsischen Landesärztekammer**

Secondary IDs

Health condition or Problem studied

- ICD10: **H81.1 - Benign paroxysmal vertigo**

Interventions/Observational Groups

- Arm 1: **patients with BPPV:Comparison of the amplitudes and latencies of VEMP (vestibular evoked myogenic potentials) before and after Dix-Hallpike / Semont /Epley manoeuvre and between healthy persons and persons suffering from BPPV**
- Arm 2: **healthy subjects: Comparison of the amplitudes and latencies of VEMP (vestibular evoked myogenic potentials) before and after Dix-Hallpike / Semont /Epley manoeuvre and between healthy persons and persons suffering from BPPV**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Prognosis**
- Assignment: **Parallel**
- Phase: **N/A**
-

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Assignment: **Parallel**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Comparison of the amplitudes and latencies of VEMP (vestibular evoked myogenic potentials) before and after Dix-Hallpike / Semont /Epley manoeuvre

Secondary Outcome

Comparison of the amplitudes and latencies of VEMP between healthy persons and persons suffering from BPPV

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **HELIOS Klinikum Borna, HNO-Klinik, R. Virchow-Strasse 2, 04552 Borna, Borna**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/01/06**
- Target Sample Size: **200**
- 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 with BPPV: suspicion of BPPV, normal clinical findings in ear microscopy, age > 18y., no use of alcohol within 12h, no acute loss of hearing, no use of sedativa or neurotological drugs, no neurological diseases
Healthy subjects: no suspicion of acute vertigo and peripheral vestibular disease, normal clinical findings in ear microscopy, age > 18y., no use of alcohol within 12h, no acute loss of hearing, no use of sedativa or neurotological drugs, no neurological diseases

Exclusion criteria

Patients with BPPV and healthy subjects: conductive hearing loss > 10 dB, age > 70y., pregnancy, lactation, incompliance, drug and alcohol abuse

Addresses

- **Primary Sponsor**

  HELIOS Klinikum Borna
  Klinik für Hals-, Nasen-, Ohrenheilkunde,
  Kopf-/Hals und plastische Gesichtschirurgie
  Mr. Dr. med. Karsten Koch
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  Telephone: **03433211476**
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  URL: **http://www.helios-kliniken.de/?id=3788**

- **Contact for Scientific Queries**

  HELIOS Klinikum Borna
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  Kopf-/Hals und plastische Gesichtschirurgie
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■ **Contact for Public Queries**

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Sources of Monetary or Material Support

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

HELIOS Resaerch Center (HRC)
HELIOS Kliniken GmbH
Friedrichstrasse 136
10117 Berlin
Germany

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.*