Trial Description

Title

Efficacy and safety of high dose glucocorticosteroid treatment for idiopathic sudden sensorineural hearing loss

Trial Acronym

HODOKORT

URL of the trial

http://hodokort-studie.hno.org/

Brief Summary in Lay Language

According to recent studies, in Germany the annually cases of sudden idiopathic sensorineural hearing loss has been estimated to be 160 to 400 per 100.000. Idiopathic sudden sensorineural hearing loss (ISSHL) is one of the most frequent causes of sensorineural hearing loss. Although sensorineural hearing impairment can be partially compensated by hearing aids (HA) or cochlear implants (CI), hearing without these aids is better with respect to sound quality and communication ability. In addition, tremendous costs for society are associated with communication disorders in general and with both aids, specifically. Systemic steroids are widely used worldwide as standard of care for primary therapy of ISSHL. However, scientific data did not demonstrate a clear efficacy of any of these therapies. The German ISSHL-Guideline recommends high dose steroid (250mg Prednisolone or equivalent steroid dose) for primary therapy of ISSHL, which has not been proven so far in high-quality scientific studies. This three-armed trial is aimed to compare standard dose with two types of high-dose steroids for systemic therapy with respect to their efficacy in improving hearing, and thus communication ability in patients with idiopathic sudden sensorineural hearing loss. It is to be tested, if high-dose treatments show superiority as compared to standard treatment.
In the course of a protocol amendment, the following changes were made in October 2017: - adjustment or clarification of the inclusion / exclusion criteria. The amendment was approved by the ethics committee of the Medical Faculty of the Martin-Luther-University Halle Wittenberg on 05.10.2017.

Brief Summary in Scientific Language

According to recent studies, in Germany the incidence of sudden idiopathic sensorineural hearing loss has been estimated to be 160 to 400 per 100.000. Idiopathic sudden sensorineural hearing loss (ISSHL) is one of the most frequent causes of sensorineural hearing loss. Although sensorineural hearing impairment can be partially compensated by hearing aids (HA) or cochlear implants (CI), generic hearing is better with respect to sound quality and communication ability. In addition, tremendous costs for society are associated with communication disorders in general and with both, HAs and CI, specifically. Systemic steroids are widely used worldwide as standard of care for primary therapy of ISSHL. However, their assessment in reviews, meta-analysis and RCTs did not demonstrate a clear efficacy of any of these therapies. The German ISSHL-Guideline recommends high

dose steroid (250mg Prednisolone or equivalent steroid dose) for primary therapy of ISSHL, which has not been proven so far in RCTs. The rationale for the treatment of ISSHL using high dose steroids is only based on retrospective cohort studies. This three-armed trial is aimed to compare standard dose with two types of high-dose steroids for systemic therapy with respect to their efficacy in improving hearing, and thus communication ability in patients with idiopathic sudden sensorineural hearing loss.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00010738**
- Date of Registration in DRKS: **2016/07/15**
- 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.: **2016-33 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2015-002602-36**

Health condition or Problem studied

- ICD10: **H91 - Other hearing loss**

Interventions/Observational Groups

- Arm 1: **Prednisolone, 250 mg/day i.v., for 5 days (+ Placebo p.o. 10 days)**
- Arm 2: **Dexamethasone, 40 mg/day p.o., for 5 days (+ Placebo i.v. 5 days/ p.o. 5 days)**
- Arm 3: <style fontName='DejaVu Sans' isBold='true'>Prednisolone, 60 mg/day p.o., für 5 days & Prednisolone in tapering doses (2 x 40 mg and 3 x 20 mg), for 5 days (+ Placebo i.v. in the first 5 days)</style>

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, assessor**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **Yes**

Primary Outcome

Average change in hearing thresholds (pure-tone average of the 3 most affected contiguous frequencies)

Secondary Outcome

-average change in pure tone hearing level (3PTA0,5-2kHz [Fletcher- Typ] und 4PTA0,5-4kHz) 30 days after enrolment
-percentage of patients with complete, partial or no improvement of hearing
-average change in percentage of ear-specific masked monosyllabic words understood correctly at 65 and 80 dB SPL
-patient self evaluation, quality of life and communication competence (patient questionnaires SF-12, HHIE)
-percentage of patients needing a hearing aid/ cochlear implant
-percentage of patients with new or worsened arterial hypertension at day 5 (office blood pressure >140 mmHg syst. or >90 mmHg diast. or both)
-percentage of patients with altered glucose tolerance at day 5 (to be detected by HOMA-IR)
-need for rescue therapy
-occurrence and extent of tinnitus one and six month after enrolment

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Halle Saale**
- University Medical Center **Jena**

- Medical Center **Berlin**
- Medical Center **Gera**
- University Medical Center **Regensburg**
- University Medical Center **Magdeburg**
- University Medical Center **Greifswald**
- Medical Center **Dessau**
- Medical Center **Nordhausen**
- University Medical Center **Lübeck**
- Medical Center **Stuttgart**
- University Medical Center **Bochum**
- Medical Center **Halberstadt**
- University Medical Center **Leipzig**
- University Medical Center **Ulm**
- University Medical Center **Freiburg im Breisgau**
- Doctor's Practice **Starnberg**
- University Medical Center **Essen**
- Medical Center **Bad Lippspringe**
- University Medical Center **Rostock**
- University Medical Center **Erlangen**
- University Medical Center **Münster**
- Medical Center **Zwickau**
- Medical Center **Suhl**
- University Medical Center **Hannover**
- University Medical Center **Erfurt**
- University Medical Center **Kiel**
- University Medical Center **Gießen**
- University Medical Center **Aachen**
- University Medical Center **Dresden**
- Medical Center **Mönchengladbach**
- Doctor's Practice **Essen**
- Medical Center **Karlsruhe**
- University Medical Center **Frankfurt a.M.**

- University Medical Center **Köln**
- University Medical Center **Tübingen**
- Doctor's Practice **Bad Schönborn**
- Medical Center **St. Georg, Leipzig**
- Doctor's Practice **Berlin**
- Medical Center **Bad Hersfeld**
- University Medical Center **Mannheim**
- Doctor's Practice **Landsberg a. Lech**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/11/28**
- Target Sample Size: **312**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

-female and male adults (18-80 years)
-unilateral sensorineural hearing loss
-sudden onset of hearing loss (occurring within 24 hours)
-unknown etiology (no other ear or CNS disease)
-change in hearing threshold due to ISSHL of 30 dB or higher compared to a pre-event audiogram, the audiogram of the unaffected ear, or the ISO) for the 3 most affected contiguous frequencies in the affected ear but not less then 50 dB absolute threshold as average of the 3 most affected contiguous frequencies between 0,25 und 8 kHz
-enrolment and treatment within 7 days from onset

Exclusion criteria

-recurrent ISSHL at the affected side (< 12 months)
-known other otologic cause of ISSHL (e.g.: middle ear disease; vestibular schwannoma; known fluctuating hearing loss; Meniere’s disease)
-absolute hearing threshold as average of the 3 most affected contiguous frequencies between 0,25 und 8 kHz < 50 dB HL
-certain systemic diseases (treatment for or chronically active infection such as HIV, hepatitis C or B, tuberculosis, hard to balance diabetes mellitus, ongoing

immunosuppressive treatment for rheumatic or chronic inflammatory disease, unstable atherosclerotic disease, heart failure >NYHA II, suicidality, severe osteoporosis, active peptic ulcer, uncontrolled (syst. >180 mmHg or diast. >100 mmHg) arterial hypertension)
-treated mental disorders or after surgical interventions in the last 6 weeks: inclusion only after critical evaluation by the investigator
-pre-treatment of ISSHL with glucocorticosteroids or hyperbaric oxygen
-conductive deafness (air-bone gap 4PTA0,5-4kHz >10 dB)
-pregnancy or lactation

Addresses

■ **Primary Sponsor**

Martin-Luther-Universität Halle-Wittenberg
06097 Halle (Saale)
Germany

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

■ **Contact for Scientific Queries**

Universitätsklinik für Hals-Nasen-Ohrenheilkunde, Kopf- und Halschirurgie
Mr. Prof. Stefan Plontke
Ernst-Grube-Str. 40
06120 Halle (Saale)
Germany

Telephone: **+49 3455571784**
Fax: **[---]***
E-mail: **stefan.plontke at uk-halle.de**
URL: **[---]***

■ **Contact for Public Queries**

Universitätsklinik für Hals-Nasen-Ohrenheilkunde, Kopf- und Halschirurgie oder Prüfärzte am jeweiligen Standort,
Mr. Prof. Stefan Plontke
Ernst-Grube-Str. 40
06120 Halle (Saale)
Germany

Telephone: **+49 3455571784**
Fax: **[---]***
E-mail: **stefan.plontke at uk-halle.de**
URL: **[---]***

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.)**

  Bundesministerium für Bildung und Forschung
  53175 Bonn
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.bmbf.de**

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2020/09/16**

Trial Publications, Results and other documents

Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.