Trial Description

Title

Prospective randomised multi-centre trial (Phase III) on the improvement of cochlear and facial nerve functions after vestibular schwannoma surgery by prophylactic vasoactive treatment.

Trial Acronym

AkNiPro

URL of the trial

[---]*

Brief Summary in Lay Language

Facial nerve paresis and hearing loss are common complications after vestibular schwannoma surgery. The purpose of this clinical research study is to see if adding a prophylactic treatment consisting of nimodipine and hydroxyethylstarch one day prior until seven days after the surgery may help to reduce the complications named above. This treatment has not yet been established in clinical routine, however, preceding studies showed promising results on patients receiving prophylactic treatment. To confirm the positive effect on the preservation of facial and hearing nerve functions on a higher number of patients the present study was initiated. In the future, vasoactive treatment may be recommended as a routine therapy.

Brief Summary in Scientific Language

Depending on the size of the tumor and the preoperative function of the facial and vestibular nerves, facial nerve paresis and hearing loss are common complications after vestibular schwannoma surgery. A Pilot-study with 30 patients (Neurosurgery, 2007 Jul;61(1):92-7; discussion 97-8) showed a beneficial effect of prophylactic treatment consisting of nimopidine and hydroxyethylstarch on preservation of facial and cochlear nerve functions in vestibular schwannoma surgery. To confirm these results as well as to increase the scientific power a prospective, randomised clinical trial (Phase III) with a higher number of patients is needed.

Organizational Data

- DRKS-ID: **DRKS00000328**
- Date of Registration in DRKS: **2010/02/17**
- 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.: **AkNiPro , Ethikkommission der Medizinischen**

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Ethics Approval/Approval of the Ethics Committee: **Approved**
Fakultät der Martin-Luther-Universität Halle Wittenberg

Secondary IDs

- Universal Trial Number (UTN): **U1111-1113-5499**
- EudraCT-No.
(for studies acc. to Drug Law): **2009-012088-32**
- BfArM-No.: **4035768**
- Sponsor-ID: **KKSH-066 (Martin-Luther-Universität Halle-Wittenberg)**

Health condition or Problem studied

- MedDRA: **LLT 10000522: Acoustic neurinoma**
- ICD10: **D33.3 - Benign neoplasm: Cranial nerves**

Interventions/Observational Groups

- Arm 1: **Surgery plus prophylactic vasoactive treatment consisting of nimodipine (Nimotop® S 5-10 ml/h (1-2 mg/h) i.v.) and hydroxyethylstarch (Voluven® 6%, aim at a hematocrit 30-35%, max. 2 x 500 ml/d, i.v.) which start the day before surgery and to be continued until the seventh postoperative day**
- Arm 2: **Surgery without prophylactic vasoactive treatment. When intra-operative monitoring show signs of a deterioration of facial or cochlear nerve function, vasoactive treatment consisting of nimodipine (Nimotop® S 5-10 ml/h (1-2 mg/h) i.v.) and hydroxyethylstarch (Voluven® 6%, aim at a hematocrit 30-35%, max. 2 x 500 ml/d, i.v.) will be started immediately. Vasoactive treatment will then be continued until the seventh postoperative day.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***

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

Allocation: **Randomized controlled trial**

Blinding: **[---]***

- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Binary outcome value. Deterioration of facial nerve functions 12 month after surgery for at least 1 grade (House-Brackmann classification)

Secondary Outcome

Facial nerve functions once during the first 7 days postoperatively as well as 3, 6 and 12 month after surgery compared to the preoperative situation determined using the House-Brackmann classification. || Cochlear nerve functions once during the first 7 days postoperatively and 12 month after surgery determined using the following classifications
a)"Committee on Hearing and Equilibrium guidelines for the evaluation of hearing preservation in acoustic neuroma (vestibular schwannoma)"
b) Grading of hearing loss according Gardener and Robertson

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/01/27**
- Target Sample Size: **112**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2010/01/27**

Target Sample Size: **112**

- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Age >= 18 years
- Male or female patients who are able to give informed consent
- Acoustic neuroma, indication for surgery
- Written informed consent

Exclusion criteria

- Contraindication for the administration of study drug (nimodipine, hydroxyethylstarch)
- Concurrent treatment with other experimental drugs or participation in another clinical trial with any investigational drug within 30 days prior to study screening
- History of critical interactions between nimodipine and other potentially nephrotoxic agents such as aminoglycosids, cephalosporids, furosemid
- Preoperative facial nerve function House-Brackmann grade VI
- Preliminary surgery of the acoustic neuroma
- Pregnancy and lactation
- Incompliance
- Participation in another clinical trial with any investigational drug within 30 days prior to study screening
- Other reasons for inability to undergo surgery
- Neurofibrimatosis type 2

Addresses

- **Primary Sponsor**

  Martin-Luther-Universität Halle-Wittenberg
  Medizinische Fakultät
  Magdeburger Str. 8
  06112 Halle (Saale)

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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E-mail: **[---]***
URL: **http://www1.medizin.uni-halle.de/pdf/**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/02/26**

Trial Publications, Results and other documents

- Paper **J Neurosurg. 2016 Nov;125(5):1277-1282. Epub 2016 Jan 29.**

** 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.*