**Trial Description**

**Title**

Sensation loss and Frey’s syndrome after superficial parotidectomy for benign parotid lesions

**Trial Acronym**

[---]*

**URL of the trial**

[---]*

**Brief Summary in Lay Language**

Several postoperative complication may appear after a parotidectomy. Besides the facial nerve paralysis, the Frey’s syndrome and the sensation loss appear as the most common concerns of the patients. There are several intraoperative techniques, which are reported to influence the a. gustatory sweating and b. the sensation loss.

For a. The interposition of the sternocleidomastoid muscle flap was reported to minimize the rate of postoperative Frey’s syndrome. For b. the role of the preservation or sacrifice of the great auricular nerve is unclear. The aim of this trial was to analyze the prevalence of Frey’s syndrome (a) and sensation loss (b) in patients with a benign parotid lesions, who underwent a superficial parotidectomy. The occurrence of Frey’s syndrome was correlated to the interposition of the sternocleidomastoid muscle flap. The sensation loss was correlated to the integrity of the great auricular nerve.

**Brief Summary in Scientific Language**

The superficial parotidectomy is a common surgical procedure for treatment of benign parotid tumors. Besides the facial nerve palsy, there is a risk of complications as Frey’s syndrome and sensation loss of the preauricular area after the surgery.

Several procedures were described to minimize the occurrence of Frey’s syndrome. Still, there is no generally accepted procedure described in randomized prospective trials, which influence the rate of Frey’s syndrome significantly. The studies often include malignant lesions as different types of surgery. The one of the most common procedures, which a described to minimize the rate of Frey’s syndrome is the interposition of sternocleidomastoid muscle flap. The other problem is the sensation loss after the surgery. There are several trials, which contained a small group of participants, with a description of a favourable effect of intraoperatively protected great auricular nerve.

The aim of this trial was to analyze the prevalence of Frey’s syndrome (a) and sensation loss (b) in patients with a benign parotid lesions, who underwent a superficial parotidectomy. The occurrence of Frey’s syndrome was correlated to the interposition of the sternocleidomastoid muscle flap. The sensation loss was...
correlated to the integrity of the great auricular nerve.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: DRKS00008972
- Date of Registration in DRKS: 2015/07/30
- 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.: 10-171, Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln

Secondary IDs

ICD10:
- D37.0 - Neoplasm of uncertain or unknown behaviour: Lip, oral cavity and pharynx

Health condition or Problem studied

ICD10:
- D37.0 - Neoplasm of uncertain or unknown behaviour: Lip, oral cavity and pharynx

Interventions/Observational Groups

- Arm 1: The sternocleidomastoid muscle flap is dissected and interposed in patients, which undergo parotidectomy because of a benign tumor. The flap dissection is study-related; the flap is interposed, if the parotid specimen (incl. tumor) intraoperatively displaces a formaldehyde volume >25ml
- Arm 2: The indication for parotidectomy is not study-related. The dissection of the sternocleidomastoid flap is study-related: the muscle flap is not dissected, if the parotid specimen (incl. tumor) intraoperatively displaces a formaldehyde volume <25ml
- Arm 3: In patients with an indication for parotidectomy the status of the great auricular nerve is evaluated: The nerve or its posterior branch is preserved, if possible.
The randomisation of this surgical step is not possible because of high variability in anatomy of the great auricular nerve and the localization of the parotid tumor.

Arm 4: In patients with an indication for parotidectomy the status of the great auricular nerve is evaluated: The nerve or its posterior branch is dissected and cut. The randomisation of this surgical step is not possible because of high variability in anatomy of the great auricular nerve and the localization of the parotid tumor.

Characteristics

- Study Type: Interventional
- Study Type Non-Interventional: [---]*
- Allocation: Other
- Blinding: [---]*
- Who is blinded: [---]*
- Control: Active control (effective treatment of control group)
- Purpose: Treatment
- Assignment: Other
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A

Primary Outcome

Sensation loss and Frey´s syndrome 12 months after surgery

Secondary Outcome

Sensation loss and Frey´s syndrome 24 months after surgery

Countries of recruitment

- DE Germany

Locations of Recruitment

- University Medical Center HNO Uniklinik Köln, Köln
Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2010/10/01
- Target Sample Size: 150
- 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

- Benign lesion of the parotid gland
- Regular preoperative facial nerve function
- Primary surgery
- 18y. old or older

Exclusion criteria

- Unclear dignity of the parotid lesion or malignant lesion
- Preoperative facial nerve palsy
- Facial nerve palsy in the past
- Revision surgery
- Diseases of the peripheral nervous system or diseases which may result in a neuropathy.
- Allergy /Hypersensitivity to iod
- Pregnancy
- Diseases, which pose contraindication for general anestesia

Addresses

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Sources of Monetary or Material Support

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

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Status

Recruitment Status: Recruiting complete, follow-up complete

Study Closing (LPLV): 2014/07/11

Trial Publications, Results and other documents

Paper Frey’s syndrome after superficial parotidectomy: role of the sternocleidomastoid muscle flap: a prospective nonrandomized controlled trial

Paper Sensation loss after superficial parotidectomy: A prospective controlled multicenter trial
Please note:
There are additional attributes available concerning this trial. To open an extended view please click here.