

# The impact of injury of the chorda tympani nerve during primary stapes surgery and primary cochlear implantation on taste function, quality of life and food preferences

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Primary Objective: To evaluate the effect of CTN injury on postoperative taste function measured using taste strips in patients undergoing primary stapes surgery or primary cochlear implantation. Secondary Objective(s): - To compare the postoperative...

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| <b>Ethical review</b>        | Approved WMO                           |
| <b>Status</b>                | Recruiting                             |
| <b>Health condition type</b> | Middle ear disorders (excl congenital) |
| <b>Study type</b>            | Observational non invasive             |

## Summary

### ID

NL-OMON51173

### Source

ToetsingOnline

### Brief title

TACO study

### Condition

- Middle ear disorders (excl congenital)
- Procedural related injuries and complications NEC

### Synonym

ageusia, hypogeusia, taste disturbance

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Utrecht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Chorda tympani, Quality of life, Stapes surgery, Taste function

## Outcome measures

### Primary outcome

The main study parameter will be the 6 weeks postoperative amount of identified taste strips of the ipsilateral tongue of the operated ear. The range for possible scores is 0 to 20.

### Secondary outcome

- The difference between the preoperative and postoperative amount of identified sweet taste strips of the ipsilateral tongue of the operated ear
  - The difference between the preoperative and postoperative amount of identified salty taste strips of the ipsilateral tongue of the operated ear
  - The difference between the preoperative and postoperative amount of identified sour taste strips of the ipsilateral tongue of the operated ear
  - The difference between the preoperative and postoperative amount of identified bitter taste strips of the ipsilateral tongue of the operated ear
  - The difference between the preoperative and postoperative amount of identified umami taste strips of the ipsilateral tongue of the operated ear
- The difference between the preoperative and postoperative EGM thresholds in dB for different locations of the tongue
- The postoperative existence of metallic taste sensation

- The postoperative existence of dryness of the mouth
- The postoperative existence of tingling sensations of the tongue
- The postoperative existence of numbness of the tongue
- The difference between the preoperative and postoperative score of the AHSP questionnaire- The difference between the preoperative and postoperative score of the health-related quality of life questionnaire
- The difference between the preoperative and postoperative total and sub scores of the MTPRT
- The difference between the preoperative and postoperative odour identification score

## Study description

### Background summary

The chorda tympani nerve (CTN) is a mixed nerve, which carries sensory and parasympathetic fibers. The sensory component supplies the taste sensation of the anterior two-thirds of the ipsilateral side of the tongue. During middle ear surgery the CTN is exposed and frequently stretched or sacrificed, because it lacks a bony covering as it passes the middle ear. The injury may cause hypogeusia, ageusia or altered taste sensation of the ipsilateral side of the tongue. Patients may also suffer from a dry mouth. To date, there is no consensus regarding which type of CTN injury, obtained during primary stapes surgery and primary cochlear implantation, gives the least burden.

### Study objective

Primary Objective:

To evaluate the effect of CTN injury on postoperative taste function measured using taste strips in patients undergoing primary stapes surgery or primary cochlear implantation.

Secondary Objective(s):

- To compare the postoperative taste function of sweet, sour, bitter, salty and umami measured using taste strips in patients between two types of CTN injury

(stretching or sacrificing)

- To compare the postoperative EGM threshold in dB for different locations of the tongue in patients between two types of CTN injury (stretching or sacrificing)
- To compare the presence of postoperative symptoms of taste disturbance in patients between two types of CTN injury (stretching or sacrificing).
- To compare the postoperative perception of appetite, hunger and sensory in patients between two types of CTN injury (stretching or sacrificing).
- To compare the postoperative quality of life in patients between two types of CTN injury (stretching or sacrificing).
- To compare the postoperative enjoyment of food in patients between two types of CTN injury (stretching or sacrificing).
- To compare the postoperative food preference in patients between two types of CTN injury (stretching or sacrificing).
- To compare the postoperative odour identification score in patients between two types of CTN injury (stretching or sacrificing)

## **Study design**

The study design is illustrated in Figure 1 of the protocol: C1. Patients participate after Informed Consent (IC) is obtained. This is a prospective multicenter study. It will run for approximately four years in the UMCU and Deventer Hospital. Evaluation will take place preoperatively and at 1 week, 6 weeks and 6 months postoperatively by means of taste strip test (TST), electrogustometer (EGM), Macronutrient and Taste Preference Ranking Task (MTPRT) and questionnaires. Preoperatively and 1 week postoperatively the patient's olfactory function will be evaluated using the Sniffin\* Sticks test. Three months after surgery the taste sensation is evaluated at home using questionnaires.

## **Study burden and risks**

Patients will not experience any risks during participation in the study. There will be four test sessions. Each time, all participants complete two taste tests and a macronutrient and taste preference ranking task and fill out several sets of questionnaires. The test sessions will take place in the University Medical Center Utrecht during the regular visits of the patient to the hospital. Three months after surgery the taste sensation is evaluated at home using questionnaires. The study burden is moderate. We believe that the burden is in proportion to the potential value of the research.

## **Contacts**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Signed informed consent form
- Age  $\geq$  18 years
- Patients who are planned to undergo primary stapes surgery or primary cochlear implantation
- Willingness and ability to participate in all scheduled procedures outlined in the research protocol
- Good understanding of the Dutch language

### Exclusion criteria

- Previous middle ear surgery (with the exception of the placement of ventilation tubes in childhood)
- History of chemotherapy and/or radiotherapy
- History of facial nerve palsy
- Cardiac pacemaker

- Disability that could interfere with taste evaluation and/or questionnaire fulfilment
- Pregnancy
- History of orofacial pain
- History of dysesthesia in the orofacial region
- Local evidence of a pathological condition of the oral mucosa

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 26-10-2021

Enrollment: 154

Type: Actual

### Medical products/devices used

Generic name: Electrogustometer

Registration: Yes - CE intended use

## Ethics review

Approved WMO

Date: 08-09-2021

Application type: First submission

Review commission: METC NedMec

Approved WMO

Date: 15-02-2024

Application type: Amendment  
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

| Register | ID             |
|----------|----------------|
| CCMO     | NL76749.041.21 |