Taste function after chorda tympani injury

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20460

Source
NTR

Brief title
TACO

Health condition

loss of taste function; sensorineural hearing loss; deafness; conductive hearing loss; otosclerosis

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: University Medical Center Utrecht

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• To compare the postoperative EGM threshold in uA 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 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 or primary cochlear implantation, gives the least burden. Some articles concluded that the taste outcome is better if the CTN is sacrificed instead of the CTN being preserved but damaged by stretching. Other articles report that sacrificing the CTN results in more taste disturbance compared to nerve preservation. A lack of high quality studies on the subject precludes firm evidence-based recommendations and demonstrates the need for a high-quality study. In order to accommodate this need, in the proposed double-blind prospective study we will investigate the prognostic effect of CTN injury on postoperative taste disturbance and quality of life.

Study objective

Sacrificing the chorda tympani causes less taste disfunction than stretching or damaging the chorda tympani nerve.

Study design

• Preoperative
• 1 week postoperative
• 6 weeks postoperative
• 6 months postoperative

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

• Signed Informed Consent form
• Age ≥ 18 years
• Scheduled or on the waiting list of primary stapes surgery or primary cochlear implantation
• Willingness and ability to participate in all scheduled procedures outlined in the study protocol
• Good understanding of the Dutch language

Exclusion criteria

• Previous middle ear surgery (with the exception of the placement of ventilation tubes in childhood)
• Disability that could interfere with taste evaluation and/or questionnaire fulfilment
• History of chemotherapy and/or radiotherapy
• History of facial nerve palsy

• Cardiac pacemaker
• 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
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-10-2021
Enrollment:	154
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
Not applicable

Ethics review

Positive opinion

Date:	13-10-2021
Application type:	First submission

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
NTR-new	NL9791
Other	METC UMC Utrecht : METC 21-466

Study results

Summary results
Not applicable