

# A study on the effects of radiotherapy on hearing in patients with unilateral parotid gland tumors

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1. To determine the incidence of clinical relevant hearing loss in patients who underwent postoperative radiation for a parotid tumor.
2. To determine factors influencing hearing loss.
3. To determine the social impact of eventual hearing loss.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Aural disorders NEC
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON32836

### Source

ToetsingOnline

### Brief title

RTototox

### Condition

- Aural disorders NEC

### Synonym

ototoxicity hearing loss

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

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

## Intervention

**Keyword:** ototoxicity, parotid tumors, radiotherapy

## Outcome measures

### Primary outcome

Hearing loss

Prognostic parameters of hearing loss

Social impact of hearing loss

### Secondary outcome

Prognostic parameters of hearing loss

Social impact of hearing loss

## Study description

### Background summary

30% of the patients who were treated by surgery and radiotherapy for a parotid tumor develop hearing loss. There is a dose-effect relation of radiotherapy and hearing loss. Using modern radiation techniques it might be expected that hearing loss will decrease.

### Study objective

1. To determine the incidence of clinical relevant hearing loss in patients who underwent postoperative radiation for a parotid tumor.
2. To determine factors influencing hearing loss.
3. To determine the social impact of eventual hearing loss.

### Study design

Using audiometry and a questionnaire hearing loss was measured. The mean dose on middle ear, cochlea and Eustachian tube was estimated with a CT-planning system.

### Study burden and risks

Routine audiometry and a questionnaire will be used.

## Contacts

### Public

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De Boelelaan 1117

1081 HV

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

1. Patients with benign or malignant parotid tumor
2. Unilateral treatment by surgery and postoperative radiotherapy
3. Treated after 01-01-2000
4. Treatment with curative intent
5. No other ototoxic treatment
6. No signs of recurrence and/or distant metastases

## Exclusion criteria

Preexistent asymmetric hearing loss

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-11-2009

Enrollment: 80

Type: Actual

## Ethics review

Approved WMO

Date: 29-10-2009

Application type: First submission

Review commission: METC Amsterdam UMC

## 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

CCMO

### ID

NL29529.029.09