

# Oral function after oncological intervention, reconstruction and rehabilitation in the oral cavity

Published: 19-12-2006

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The aim of this study is to objectively and subjectively characterise different aspects of oral function for malignancy of the oral cavity.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Head and neck therapeutic procedures
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON43740

### Source

ToetsingOnline

### Brief title

QuOFu

### Condition

- Head and neck therapeutic procedures

### Synonym

Cancer, oral function

### 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:** oncology, oral function, quality of function, quality of life

## Outcome measures

### Primary outcome

1. What are objective normal values for oral function within different types of oncological patients?
2. What is the change in time of objective oral function?
3. What is the change in time of subjective oral function?
4. Are objective function and subjective oral function linked?
5. What is the difference in oral function-outcome between patients and healthy persons on the different measure-moments in time?

### Secondary outcome

6. What is the influence of reconstruction on oral function?
7. What is the influence of rehabilitation on oral function?
8. Is implant treatment before radiation therapy more effective than after radiation therapy?
9. Is oral function better after palliative intervention for big tumors (>T3) as compared to surgical intervention?

## Study description

### Background summary

In The Netherlands the total incidence of squamous cell carcinomas of the head and neck in 2002 was more than 2300. Approximately 32% of the newly diagnosed head and neck tumors occur in the oral cavity. In 1997 the mortality was about 56% (after 5 years) for malignancy in the oral cavity. After surgical

intervention and/or radiation therapy (oral) function is deteriorated. A decrease of quality of function can be observed in a.o. speech, chewing, swallowing, and saliva secretion. The oral function is essential for quality of life. This study is unique, because there are no objective long-term oral function outcomes published.

### **Study objective**

The aim of this study is to objectively and subjectively characterise different aspects of oral function for malignancy of the oral cavity.

### **Study design**

This study is a prospective cohort-research.

### **Study burden and risks**

This is not applicable

## **Contacts**

### **Public**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

\* Malignancy in the mouth at first time

\* Adult

### Exclusion criteria

Persons who are disable to fill in questionnaires

## Study design

### Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

**Primary purpose:** Health services research

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 03-01-2007

Enrollment: 145

Type: Actual

## Ethics review

Approved WMO

Date:	19-12-2006
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	09-11-2016
Application type:	Amendment
Review commission:	METC NedMec

## 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	NL12006.041.06

## Study results

Date completed:	24-04-2019
Actual enrolment:	145

### Summary results

Trial is ongoing in other countries