Function after a maxillectomy reconstructed with an obturator

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Evaluation of function of maxillectomy patients after prosthetic obturation, related to the extent of the defect.

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON32896

Source
ToetsingOnline

Brief title
Function after maxillectomy

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified
- Head and neck therapeutic procedures

Synonym
tumor invading the maxillary sinus, upper jaw tumor

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chewing function, maxillectomy, obturator, quality of life

Outcome measures

Primary outcome

Primary outcome measurements:

- nasalance on a VAS score

- maximal mouthopening

- mixing ability index

- quality of life and obturator functioning questionnaires

stratified for:

- size of maxilla defect (Brown classification)

- remaining percent hard palate and soft palate contralaterally

- resection of the premaxilla

- history of adjuvant radiotherapy

- presence of natural dentition

Secondary outcome

Primary outcome measurements stratified for:

- age

- sex

Study description

Background summary

Patients are after a maxillectomy often reconstructed with a prosthetic obturator. This is a simple and effective way to fill up the defect that exists after tumorablative surgery and to prevent problems with eating and speaking. There is relatively little literature about the function after such a reconstruction. Some small studies with confined patient groups show that function is well recovererd after surgery, but extent of the resection influences the functional result.
Nowadays, there is a second curative therapy modality for patients with head and neck cancer, namely organsparing therapy, chemoradiation. Inoperable tumors are being treated with curative chemoradiation, but some patients will be advised primary chemoradiation if the tumor is so large that after extensive surgery a big functional loss may be expected. This is called functional inoperability.
In order to make a careful patient selection for different treatment options, and to be able to provide meaningful preoperative patient counselling about the expected postoperative result after a maxillectomie, we aim at evaluating functionality after a maxillectomy and prosthetic rehabilitation. The function will be related to the extent of resection, dentition and a history of probable adjuvant radiotherapy, in order to find significant anatomic and preoperatively known patient-bound factors that deteriorate function, namely mastication, nasalance, trismus and quality of life.

Study objective

Evaluation of function of maxillectomy patients after prosthetic obturation, related to the extent of the defect.

Study design

Retrospective cohort study

Study burden and risks

Burden for participating patients is an extra visit to the Antoni van Leeuwenhoek Hospital, once only, lasting 30 minutes. There is no extra risk involved.

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

Patients
- having undergone a maxillectomy 1998-2008
- reconstructed with an obturator
- controlled by the dentists/ maxillofacial prosthetics of the Antoni van Leeuwenhoek Hospital

Exclusion criteria

Patients
- that are not mobile or healthy enough to come for an extra visit to the hospital
- having a local recurrence which is not possible to treat anymore, or still planned to be treated
- with lack of basic written and oral command of the Dutch language
- without dental reconstruction at the moment
- with erious psychiatric or cognitive problems that would preclude completion of self-report questionnaires
- living more than 45 minutes distance from the AvL, if it is not possible to combine the visit with a control visit

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL29853.031.09