Intraoperative control of maxillary malignancy resection with cone-beam computed tomography

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Primary Objective1. Investigate the feasibility of intraoperative imaging with CBCT in open maxillectomy for verifying resection of the intended treatment volume. 2. Assess the feasibility of the intended treatment volume segmentation and resection...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Head and neck therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON43222

Source
ToetsingOnline

Brief title
Image guided maxillectomy

Condition

- Head and neck therapeutic procedures

Synonym
maxillary cancer, upper jaw malignant 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: cone-beam computed tomograply, maxillary cancer, maxillectomy

Outcome measures

Primary outcome

* Technical feasibility of determining and marking of the planned treatment

volume in the preoperative MRI.

* Technical feasibility of obtaining intraoperative CBCT of the maxilla.

* Assessment of the quality of matching (CBCT and MRI) by using the *Sorensen-

Dice coefficient* and *Hausdorff distance*.

* Rate of complete resection achieved compared to the preoperatively planned

treatment volume.

Secondary outcome

Not applicable

Study description

Background summary

Maxillary malignant neoplasms constitute a group of tumours that present often at an advanced stage. Their surgical management can be, thus, challenging, regarding also their proximity to significant structures like the orbit and the brain. Particularly, cases with extensive disease and recurrent tumours are often incompletely resected and local failure is commonly observed, ranging from 30% to 50%. The use of intraoperative imaging can be an additional tool for verifying the complete tumour resection.

Study objective

Primary Objective
1. Investigate the feasibility of intraoperative imaging with CBCT in open maxillectomy for verifying resection of the intended treatment volume.
2. Assess the feasibility of the intended treatment volume segmentation and

resection planning based on the preoperative imaging.

Study design

This is a prospective study which has the character of an exploratory pilot study, establishing the implementation of CBCT in patients undergoing maxillectomy for malignant tumours.

Intervention

Preoperative imaging with MRI of the maxilla will be obtained for all patients. Segmentation of the resection area will be then performed on the coronal and transverse sections of the MRI scans of each patient.

The study will be performed in two distinct phases:

* In the first phase, three patients will undergo the conventional open maxillectomy procedure and the intraoperative imaging with the CBCT. Comparison of the preoperative and intraoperative scans will be conducted, using imaging fusion of the MRI and the CBCT scans. No further intervention will be applied to this group, independently of the result of the intraoperative imaging.

* In the second phase, three patients will also undergo the primary resection and the intraoperative imaging. However, if the comparison of the preoperative with the intraoperative imaging reveals residual tumour that is included in the preoperative imaging resection planning, then the surgical procedure will continue in order to excise the target tissue. In this case a second CBCT will be carried out to confirm the complete resection.
Three patients will be recruited for each phase of the study.

Study burden and risks

Burden:
The burden for the individual patient is the extra operating time it takes due to additional imaging procedure (approximately 15 minutes for each CBCT scan).

Risks:
Open maxillectomy is a well-established, routine treatment modality and the general risks are well known. The only extra risk involves the additional exposure to ionizing radiation, although the dose of a CBCT scan is significantly lower than that of a conventional CT of the head and neck.

Benefits:
For the patient: The surgeon*s experience is a significant factor for complete tumor excision and, thus, for a successful maxillectomy. In this study, control of the resected area will be performed based on the comparison of the

intraoperative CBCT with the preoperative imaging (MRI) planning. This way, complete tumour resection (according to imaging) will be confirmed. Resection free margins according to intraoperative imaging can potentially increase the possibility of pathologically free margins, which in turn is a major predictive factor of prolonged survival. Moreover, the use of imaging provides an additional tool for the control of the proximity to significant anatomical structures, and thus decreasing the complication rates.
Benefits in general: The use of CBCT suggests an innovative imaging technology that may have an important contribution in the radical excision of maxillary malignant tumours, affecting positively on the patients* prognosis. Thus, the current study may have a significant impact on the way the procedure is nowadays performed.

Contacts

Public
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL
Scientific
Antoni van Leeuwenhoek Ziekenhuis

Plesmanlaan 121
Amsterdam 1066 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Primary tumours of the maxilla (T1-T4a for non-melanomas and T3-T4a for melanomas), confirmed by biopsy. Recurrent cases are also eligible.
* Any lymph node status
* M0 status
* Treatment plan approved by the multidisciplinary Head and Neck oncology meeting of the AvL
* Age over 18-years old
* No contraindications to general anesthesia
* Informed consent, written and signed

Exclusion criteria

* Unresectable tumours of the maxillary sinus
* Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol
* Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-03-2017
Enrollment:	6
Type:	Actual

Medical products/devices used

Generic name:	Cone-beam computed tomography

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2016
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	NL59005.031.16

Study results

Date completed:	02-11-2017
Actual enrolment:	6

Summary results
Trial is onging in other countries