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Image-guided maxillectomy

Submission date
05/02/2018

Recruitment status
No longer recruiting

Registration date
13/02/2018

Overall study status
Completed

Last Edited
01/04/2019

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Maxillary sinus cancer is a cancer in the area of the nose and nasal cavity. Despite extensive use of cone-beam computed tomography (CBCT) in planning surgeries to treat head and neck surgery, it has not been used before for assess the margins of tumours in maxillary cancer, where 30 to 50% of surgical resections (removals) result in incomplete removal of the tumor. CBCT is a medical imaging technique that uses the x-rays in a cone shape to create images. Therefore, with the goal of improving complete resection rates of maxillary cancer surgery, CBCT could be used during surgery. The aim of this study is to investigate the feasibility of intraoperative (during operation) of CBCT imaging to improve the amount of complete removals in maxillary cancer.

Who can participate?
Adults aged 18 and older diagnosed with maxillary cancer and scheduled for open maxillary resection (i.e. maxillectomy).

What does the study involve?
Participants undergo scans (MRI and CT scans) of their tumours. Participants then undergo their planned surgery. Next, surgical resection was preformed according to the standard practice. At the end of the surgery, a CBCT scan is done, in order to evaluate the resection by comparing preoperative resection plan and the other images, based on bone anatomy. If needed, further resections are performed and evaluated with a second CBCT scan. The differences are compared after the surgeries.

What are the possible benefits and risks of participating?
There are no direct benefits or risks with participating.

Where is the study run from?
The Netherland Cancer Institute Antoni van Leeuwenhoek Hospital (Netherlands)

When is the study starting and how long is it expected to run for?
November 2016 to November 2017

Who is funding the study?
The Netherland Cancer Institute Antoni van Leeuwenhoek Hospital (Netherlands)

Who is the main contact?
Dr Baris Karakullukçu (Scientific)

Study website
https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL 59005.031.16

Study information

Scientific Title
Intraoperative verification of maxillary malignancy resection with cone-beam computed tomography

Acronym
N16IGM

Study objectives
The primary objective of this study is to assess the feasibility of utilizing intraoperative cone-beam CT (CBCT) to verify the intended excision margins of maxillary malignant tumours. CBCT images are matched with a preoperative planning of the resection margins on the preoperative MRI. This study is the first step before conducting a randomised controlled study that evaluates the efficacy of CBCT verified resection.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee (METC) Antoni van Leeuwenhoek Hospital, 16/12/2016, ref: NL59005.031.16

Study design
Prospective exploratory single centre pilot study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Maxillary sinus malignancies

Interventions
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. Patients with maxillary sinus malignancies are included irrespectively of histological type, first presentation of disease or recurrence, that undergo open maxillectomy, as indicated. This applies to stages T1-T4a for non-melanomas (SCC, adenocarcinoma, adenoid-cystic carcinoma, etc) and T3-T4 a for melanomas of the maxilla. All participants undergo preoperative MRI and planning of the resection volume using an in-house developed medical imaging processing software.

There are two phases in this study:
1. In the first phase, three participants undergo the standard surgical procedure and control with intraoperative CBCT, without any further resection.
2. In the second phase, three participants undergo the same procedure as in phase 1, but receives additional excision if the CBCT reveals residual tissue that was included in the preoperative imaging planning.

All patients included in the study have disease that can be managed by open maxillectomy. In general, and depending on the extension of the tumour, different approaches can be used for an open maxillectomy. Common incisions include the lateral rhinotomy, the Weber-Ferguson incision or the modified Weber-Ferguson incision with a Lynch extension. The resection may include one of the following procedures:

1. Medial maxillectomy: The extent of bone resection includes the inferior and middle turbinates and ethmoid air cells cephalad and to the floor of the nasal cavity. It is indicated for well-differentiated or low-grade malignant tumours and other tumours of limited extent on the lateral wall of the nasal cavity or the medial wall of the maxillary antrum.
2. Peroral partial maxillectomy (Infrastructure Maxillectomy), when the upper alveolar ridge or hard palate are involved.
3. Subtotal maxillectomy: A subtotal maxillectomy essentially removes the entire maxilla except the floor of the orbit.
4. Total Maxillectomy: Complete removal of the maxilla becomes necessary when a primary tumour arising from the surface lining of the maxillary sinus fills up the entire antrum. Primary mesenchymal tumours arising in the maxilla such as soft tissue and bone sarcomas also require total removal of the maxilla to encompass the entire lesion.
5. Total Maxillectomy with Orbital Exenteration: A radical maxillectomy with orbital exenteration is indicated when a primary tumor of the nasal cavity or paranasal sinuses extends into the orbit through the orbital periosteum. Orbital exenteration of a functioning eye with normal vision is considered only if the possibility of a curative resection exists. Removal of a functioning eye for a palliative operation is not recommended.
6. Total Maxillectomy with Orbital Exenteration and Reconstruction with Free Tissue Transfer.

After completion of the resection, intraoperative CBCT is obtained. The participants included in the second phase of the study may receive further resection and a second CBCT scan to confirm that the intended treatment volume is resected.
At 48 hours after the surgery, participants exit the study. No further follow-up monitoring are performed, and the participants receive standard care at the treating hospital.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Feasibility of utilising CBCT as an imaging tool for intraoperative verification of maxillary malignant tumours is evaluated by comparing intraoperative assessment of surgical resections, based on quantitative comparison of preoperatively planned and actually resected bone volumes, with the pathology.
2. Mean times of the procedure are measured as the complete surgical overhead caused by study-related steps (this includes sterile intraoperative cone-beam CT scan and quantitative evaluation of the results)
3. The completeness of surgical resections are estimated based on remaining bonny anatomy of the maxilla visible in the intraoperative CBCT scan
4. Preoperatively planned and actually performed surgical resections are quantitatively compared by calculating “Sorensen-Dice coefficient” and the “Hausdorff distance” between corresponding bony structures

Secondary outcome measures
There are no secondary outcome measures.

Overall study start date
02/11/2016

Completion date
02/11/2017

Eligibility

Key inclusion criteria
1. Primary tumours of the maxilla (T1-T4a for non-melanomas and T3-T4a for melanomas), confirmed by biopsy. Recurrent cases are also eligible.
2. Any lymph node status
3. M0
4. Treatment plan approved by the multidisciplinary head and neck oncology meeting of the AvL
5. Aged over 18-years old
6. No contraindications to general anesthesia
7. Informed consent, written and signed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
6

Key exclusion criteria
1. Unresectable tumours of the maxillary sinus
2. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol
3. Pregnancy

Date of first enrolment
01/01/2017

Date of final enrolment
25/10/2017

Locations

Countries of recruitment
Netherlands

Study participating centre
The Netherland Cancer Institute Antoni van Leeuwenhoek Hospital
Plesmanlaan 121
Amsterdam

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1066CX

Sponsor information

Organisation
The Netherland Cancer Institute Antoni van Leeuwenhoek Hospital

Sponsor details
Plesmanlaan 121
Amsterdam
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1066CX

Sponsor type
Hospital/treatment centre

Website
https://www.avl.nl/

ROR
https://ror.org/03xqtf034

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
The Netherland Cancer Institute Antoni van Leeuwenhoek Hospital

Results and Publications

Publication and dissemination plan
At least one presentation at an international conference of interest. At least one scientific publications in a high-impact head and neck peer-reviewed journal. Study protocol can be shared. Shortened version of the protocol is available at the CCMO register (link below) under number NL59005.031.16 https://www.toetsingonline.nl/to/ccmo_search.nsf/Searchform?OpenForm

Intention to publish date
02/11/2018

Individual participant data (IPD) sharing plan

Patient level information contains private details of the patients (e.g. name, gender, age, etc), thus cannot be shared outside of the treating hospital. All patient record will be stored at the Ntherelands Cancer Institute. Interim and the final study report will be published on the website of Central Committee of Research Involving Human Subjects (CCMO) under number NL59005. 031.16.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V2	30/11/2016	01/04/2019	No	Yes
Protocol file			01/04/2019	No	No