Image guided endoscopic sinus surgery

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Intraoperative verification of paranasal sinus malignancy resection with cone-beam computed tomography will lead to a higher rate of radical resection

Ethical review	Not applicable
Status	Will not start
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20396

Source
Nationaal Trial Register

Health condition

paranasal sinus malignancy, sinus cancer

Sponsors and support

Primary sponsor: AVL
Source(s) of monetary or material Support: No funding. Investigator initiated research.

Intervention

Outcome measures

Primary outcome

The main parameter of this pilot study is the technical success of implementing CBCT during endoscopic sinus surgery as an additional tool for the control of the resection. Operating time will be recorded and the mean duration of the procedure will be calculated. Assessment of the possible residual tumour volume will be also performed based on the intraoperative CBCT, as well as comparison to the planned resection volume as calculated in the preoperative imaging planning. The quality of CBCT and MRI scan matching will also be evaluated. No correlation to clinicopathological parameters will be established in this study.

Secondary outcome

Not applicable

Study description

Background summary

Rationale: Paranasal sinus malignant neoplasms constitute a group of tumours that present often at an advanced stage. Their surgical management can therefore be 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 treatment failure is commonly observed.
Objective: The primary objective of this study is to assess the feasibility of utilizing intraoperative cone-beam CT (CBCT) to verify the intended excision volume of paranasal sinus malignant tumours. CBCT images will be matched with a preoperative planning of the resection volume on the preoperative MRI or CT. This study will be the first step before conducting a randomised control study that will evaluate the efficacy of CBCT verified resection.
Study design: Exploratory pilot study.
Study population: A total number of 6 patients, above 18 years old, with paranasal sinus cancer suitable for management with endoscopic sinus surgery will be included. All patients will undergo a pre-operative MRI scan of the maxilla for the evaluation of the local extent of the tumour. In this MRI, the tumour volume that is indented to be resected will be segmented.
The patients will be studied in two distinct phases:
1. Three patients will undergo the standard endoscopic sinus surgery and intra-operative control with CBCT, however without any further resection
2. Three patients that will undergo the endoscopic sinus surgery and intra-operative CBCT and additional excision, in case that residual tumour is observed based on the preoperative MR resection planning.
Main study parameters/endpoints: The main parameter of this pilot study is the technical success of implementing CBCT during endoscopic sinus surgery as an additional tool for the control of the resection. Operating time will be recorded and the mean duration of the procedure will be calculated. Assessment of the possible residual tumour volume will be also performed based on the intraoperative CBCT, as well as comparison to the planned resection volume as calculated in the preoperative imaging planning. The quality of CBCT and MRI scan matching will also be evaluated. No correlation to clinicopathological parameters will be established in this study.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden for the individual patient is the extra operating time it takes (approximately 15 minutes for each CBCT scan). 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 (approximately 1/3 to 1/6 of the dose). Endoscopic

sinus surgery itself is a well-established, routine treatment modality used as a standard procedure in patients with paranasal sinus malignancy. The potential benefits for the patients are also considerable. Till now the surgeon’s experience in recognizing potential residual tumour is the main factor for a successful endoscopic sinus surgery. The intra-operative use of CBCT can potentially verify the complete tumour resection, minimizing the risk of residual tumor and local treatment failure.

Study objective

Intraoperative verification of paranasal sinus malignancy resection with cone-beam computed tomography will lead to a higher rate of radical resection

Study design

Not applicable

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	31-08-2017
Enrollment:	6
Type:	Unknown

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL6377
NTR-old	NTR6561
CCMO	NL62415.031.17

Study results