

# 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

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Zal niet starten
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Observationeel onderzoek, zonder invasieve metingen

## Samenvatting

### ID

NL-OMON20396

### Bron

NTR

### Aandoening

paranasal sinus malignancy, sinus cancer

### Ondersteuning

**Primaire sponsor:** AVL

**Overige ondersteuning:** No funding. Investigator initiated research.

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

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.

# Toelichting onderzoek

## Achtergrond van het onderzoek

**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 intended 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.

### **Doel van het onderzoek**

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

### **Onderzoeksopzet**

Not applicable

### **Onderzoeksproduct en/of interventie**

Not applicable

## **Contactpersonen**

### **Publiek**

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

## Onderzoeksopzet

### Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

## Deelname

Nederland	
Status:	Zal niet starten
(Verwachte) startdatum:	31-08-2017
Aantal proefpersonen:	6
Type:	Onbekend

## Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten