Narrow band imaging in head and neck cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27129

Source
NTR

Brief title
NBI

Health condition

- All adult patients with a suspected malignant mucosal lesion of the upper aerodigestive tract
- Patients with benign upper aerodigestive tract lesions

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Olympus Nederland B.V. Zoeterwoude, The Netherlands, provides an unrestricted educational grant.

Intervention

Outcome measures

Primary outcome

- Correlation between WLI and / or
NBI with histopathological diagnosis.

- Accuracy: percentage of true results = (true positives + true negatives)/ total results.

Secondary outcome

there are 6 different substudies. Every study has its own secondary outcomes. 4 secondary goals are:

1. To identify NBI + WLI as superior to WLI alone in the early detection of local HNC recurrences after first line treatment

2. To identify NBI + WLI as a better diagnostic and staging tool in the determination of tumor field and as a consequence tumor staging than WLI alone

3. To conclude that inter-observer and intra-observer variability/reliability in the visual analysis of benign and (pre) malignant lesions in the upper aerodigestive tract is higher using NBI+WLI than WLI alone.

4. To increase reliability and decrease inter-/intra-observer variability by creating a NBIatlas which will be helpful in correct interpretation of NBI and can be used as a standard reference in ENT/head and neck oncology in order to increase earlier detection of (pre)malignant HNC lesions using NBI

Study description

Background summary

Visualization by (flexible) endoscopy of the mucosa of oral cavity, nasal cavity, pharynx and larynx is the hallmark in detection and diagnosis of mucosal benign and malignant lesions of the upper aerodigestive tract. Technical improvements resulted in distal chip endoscopes with digital image processing making blood vessels more visible using a technique called Narrow Band Imaging (NBI). NBI is a relatively new imaging technique (developed by Olympus Corporation, Tokyo, Japan) which increases the diagnostic potential of conventional white light imaging (WLI) endoscopy. NBI highlights abnormalities in the superficial vasculature of mucosal lesions by using narrow-bandwidth filters in a sequential red-greenblue illumination system. Although in other fields of medicine NBI has confirmed itself as an important diagnostic and prognostic instrument, in otorhinolaryngology and head and neck oncology, it has not yet been evaluated as an important reliable diagnostic or prognostic tool. We believe NBI should be used as a standard tool in diagnosis and treatment of patients with a (suspected) malignancy of the upper aero-digestive tract, but only after establishing its diagnostic and prognostic value in a large cohort of patients. Therefore, we planned to establish the role of NBI in improving diagnosis, clinical outcome and prognosis in head and neck cancer in six different substudies.

Study objective

Detection, diagnosis, staging, treatment outcome and prognosis of patients with a malignancy of the upper aerodigestive tract improve when Narrow Band Imaging in combination with standard (White Light) endoscopy is used.

Study design

1. when patients arive in the outpatient clinic with complaints for the first time

2. during surgery

3. follow up: every 3-6 months, depending on diagnosis.

Intervention

Observational cohort study, partially randomized controlled sub-studies.

The intervention itself is not part of the study.

Contacts

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Eligibility criteria

Inclusion criteria

- suspicion of or proven carcinoma of the oral cavity, nasal cavity, pharynx or larynx.

- suspicion of a benign lesion of the larynx

- > 18 yrs of age

- informed consent

Exclusion criteria

none

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2015
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-11-2016
Application type:	First submission

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	NL6052
NTR-old	NTR6199
Other	NL5315204215 : METC 2015/152

Study results