

ESTABLISHING THE DIAGNOSTIC AND PROGNOSTIC ROLE OF NARROW BAND IMAGING IN HEAD AND NECK CANCER

Published: 20-08-2015

Last updated: 19-08-2024

to establish the diagnostic and prognostic value of Narrow band Imaging (NBI) in head and neck cancer

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON47793

Source

ToetsingOnline

Brief title

NBI in HNC

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym

head and neck cancer, HNSCC

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

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2-05-2025

Source(s) of monetary or material Support: arts-onderzoeker wordt gefinancierd door Olympus BV Zoetermeer (niet de opdrachtgever van het onderzoek), Olympus

Intervention

Keyword: Cancer, Head and neck, HNSCC, NBI

Outcome measures

Primary outcome

Primary Objective: to validate NBI (using flexible and rigid laryngoscopes) in HNC as a prognosticator and establish NBI as a reliable diagnostic tool by discriminating (pre)malignant lesions from benign lesions

Secondary outcome

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 NBI-atlas which will be helpful in correct interpretation of NBI.

Study description

Background summary

Narrow Band Imaging (NBI) is a relatively new imaging technique used in endoscopy and increases the diagnostic potential of conventional white light imaging (WLI) endoscopy by highlighting abnormalities in the superficial

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

Study objective

to establish the diagnostic and prognostic value of Narrow band Imaging (NBI) in head and neck cancer

Study design

Observational cohort study, partially randomized controlled.

There are 6 sub-studies:

Study 1: comparison of flexible transnasal laryngoscopy with rigid microlaryngoscopy using WLI and WLI+NBI in diagnosis of both benign and malignant lesions

Study 2: radical resection rate of laser excision and recurrence free survival after laser excision using WLI or WLI+NBI

Study 3: descriptive study to determine accuracy of WLI and WLI+NBI in detecting normal and (pre)malignant mucosa

Study 4: detection of recurrences after RT using WLI or WLI+NBI during flexible transnasal laryngoscopy

Study 5: detection of recurrences after RT using WLI or WLI+NBI during rigid microlaryngoscopy under general anaesthesia

Study 6: descriptive study to determine accuracy of WLI and WLI+NBI in discriminating malignant tissue from non-malignant irradiated mucosa

Study burden and risks

Burdens: although standard diagnostic procedures are followed during follow-up of the included patients, the use of NBI besides WLI could lead to additional transnasal flexible laryngoscopies because the clinician is triggered to possible mucosal abnormalities when using NBI. This is also the case nowadays when additional flexible videolaryngoscopy is performed when the visualization is inconclusive after flexible laryngoscopy with routinely used fiberscopes .

Risks: no additional risks are to be expected, since standard diagnostic, staging, treatment and follow-up procedures are maintained. Flexible laryngoscopies are safe and additional biopsies without significant risks.

Benefits: visualization will be done using distal chip videolaryngoscopes which have a better visualization than routinely used fiberscopes. An earlier and better detection of a primary tumor or recurrent disease can be expected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

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 invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-09-2015
Enrollment:	450
Type:	Actual

Ethics review

Approved WMO	
Date:	20-08-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	21-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	05-11-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL53152.042.15