

Narrow band imaging in head and neck cancer

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27129

Bron

NTR

Verkorte titel

NBI

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Groningen

Overige ondersteuning: Olympus Nederland B.V. Zoeterwoude, The Netherlands, provides an unrestricted educational grant.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

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

Toelichting onderzoek

Achtergrond van het onderzoek

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-green-blue 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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. when patients arrive in the outpatient clinic with complaints for the first time
2. during surgery
3. follow up: every 3-6 months, depending on diagnosis.

Onderzoeksproduct en/of interventie

Observational cohort study, partially randomized controlled sub-studies.

The intervention itself is not part of the study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

none

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	10-09-2015
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	03-11-2016
Soort:	Eerste indiening

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	NL6052
NTR-old	NTR6199
Ander register	NL5315204215 : METC 2015/152

Resultaten