Optical techniques in diagnosis and management of premalignant and malignant laryngeal and pharyngeal lesions.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON39924

Source
ToetsingOnline

Brief title
Optical techniques in diagnosis of (pre)malignant laryngopharyngeal lesions

Condition

- Other condition
- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
head and neck cancer, laryngeal/pharyngeal cancer

Health condition

premaligne en maligne tumoren van de larynx en farynx

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W,Er zal een subsidie aanvraag worden gedaan bij ZonMw;hierover is op dit moment nog geen zekerheid.

Intervention

Keyword: diagnosis, head and neck cancer, laryngoscopy, optical techniques

Outcome measures

Primary outcome

The main study parameters are the assessment of the extend of mucosal pathology by video recordings of High Definition videolaryngoscopy compared with that by rigid direct laryngoscopy using a standard format for judgement of tumour extension.

Secondary outcome

Secondary study parameters are: date of first contact, standardized judgment of fiberoptic and videolaryngoscopy compared to HD videolaryngoscopy and direct laryngoscopy, standardized judgment of first videolaryngoscopy 2-3 weeks earlier and comparison with study videolaryngoscopy, date of laryngoscopy in general anaesthesia, date of start of treatment and time till start of treatment, follow up time, recurrence rate and date of recurrence, patients quality of life and voice handicap, and costs of diagnostic route.

Study description

Background summary

Major improvements have been made in flexible endoscopic tools for the assessment of mucosal and submucosal lesions in the upper aerodigestive tract. In the past decade several types of transnasal video endoscopes have been developed that are being used increasingly in otorhinolaryngology. These videolaryngoscopes show tremendous increase in visibility of detail compared to the ordinary used transnasal fiberoptic laryngoscope. And in the laryngoscopes with an instrument channel it is also possible to obtain tissue for histopathologic investigation. However, due to lack of evidence on the accuracy of these videolaryngoscopes, direct laryngoscopy under general anaesthesia has remained the gold standard for determination of the extend of laryngeal and pharyngeal lesions suspect for carcinoma and to perform biopsy.

In this study we will analyse the accuracy of new endoscopic methods in the detection and determination of the extend of laryngeal and pharyngeal epithelial lesions. If this method is proven accurate, direct laryngoscopy under general anaesthesia may no longer be needed in the routine diagnostic work-up. It will obviate the need for pre-operative consultation of anaesthesiologists, the risks of general anaesthesia in patients with often significant comorbidity and possible delays in treatment. More timely treatment is likely to result in a reduction of duration of uncertainty and anxiety for the patient. Lastly, it may decrease health care costs and improve outcome.

The endoscopes included in this study are all flexible transnasal laryngoscopes. Each of them is CE marked and currently used in daily practice in Radboud University Nijmegen Medical Centre. The fiberoptic laryngoscope, videolaryngoscope with i-scan filter and high definition (HD) videolaryngoscope with i-scan filter [Pentax, Japan] are included. A videolaryngoscope with a working channel will not be used, therewithal strict disinfestations and sterilization methods the risk of infection is negligible. I-scan is a postprocessing digital image enhancement with adjustable tonal, contrast and surface filters with the intent to increase visibility and differentiation of pathologic mucosa. In gastroenterology a prospective randomized control trial has shown significant higher detection of neoplastic lesions and more flat benign tumours when using a HD colonoscope with i-scan function compared to standard video colonoscopy [Hoffman et al, 2010].

Study objective

Primary objective is to analyse whether transnasal videolaryngoscopy in outpatient practice is more accurate in determination of the extend of the affected mucosa of laryngopharyngeal tumours compared to direct laryngoscopy under general anaesthesia; the current gold standard.

Secondary objectives are multiple:
• To study whether transnasal videolaryngoscopy in outpatient practice is more accurate in determination of the extend of the affected mucosa of laryngopharyngeal tumours compared to transnasal fiberoptic laryngoscopy.

• To assess tumour growth during waiting times for completion of the diagnostic phase by standardized judgment of first videolaryngoscopy approximately 2-3 weeks earlier and comparison with study videolaryngoscopy.
• To determine the recurrence rate in relation to the possibly more adequate delineation of the lesions with the use of transnasal videolaryngoscopy and the early detection of recurrence during follow up.
• To compare cost-effectiveness of transnasal videolaryngoscopy in outpatient practice to direct laryngoscopy under general anaesthesia.
• To ascertain patient general and disease-specific quality of life and voice handicap index.

Study design

Study design will be a prospective descriptive study.

Study burden and risks

Patients participating in this study get an extra opportunity to see video images of the tumour without any additional risk caused by the two extra transnasal laryngoscopies. Furthermore, the two quality of life questionnaires are short and don*t contain detailed intimated personal questions. Potential additional tiny (2-3 millimeters) biopsies, during rigid laryngoscopy in general anesthesia based on videolaryngoscopic image with or without i-scan filters of suspected tumour extension, are harmless and may be of great interest in precise tumour delineation and staging, and therefore accurate treatment. There are no extra visits necessary for study participation.
If videolaryngoscopy is proven to be accurate, the need for direct laryngoscopy under general anaesthesia is obviated and thereby the need for pre-operative consultation of anaesthesiologists, the risks of general anaesthesia in patients with often significant comorbidity and possible delay in treatment. More timely treatment is likely to result in a reduction of the duration of uncertainty and anxiety for the patient. Lastly, it may decrease health care costs and improve outcome.

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

All patients presented with laryngeal or pharyngeal tumours suspect for malignancy or proven to be malignant in Radboud University Nijmegen Medical Centre or Medical Centre Leeuwarden are eligible for inclusion.

Exclusion criteria

Age younger than 18 years old
Inability to undergo generals anaesthesia
Metal incompetence

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-03-2015
Enrollment:	350
Type:	Actual

Medical products/devices used

Generic name:	transnasal flexible video laryngoscope
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-11-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41474.091.13