High Definition bronchoscopy, an exploratory study of diagnostic value in comparison to standard white light bronchoscopy and autofluorescence bronchoscopy

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(1) Investigate diagnostic performance (sensitivity) of HD bronchoscopy, with or without surface enhancement or tone enhancement in comparison to standard WLB for detecting abnormalities of the tracheobronchial tree. Furthermore we aim to...

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

Summary

ID

NL-OMON35123

Source
ToetsingOnline

Brief title
HD bronchoscopy

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified
- Respiratory tract neoplasms
- Respiratory tract therapeutic procedures

Synonym
head and neck cancer, lung cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnostic bronchoscopy, Head and Neck Cancer, High Definition imaging, Lung Cancer

Outcome measures

Primary outcome

Decriptive study of diagnostic performance of HD-bronchoscopy using different imaging techniques in comparison to standard white light bronchoscopy and autofluorescence bronchoscopy in determining epithelial changes, changes in vascularity and tumour margins.

Secondary outcome

when differences are established between the different bronchcopy modes a power analysis may be performed to determine the feasibility of a prospectively designed study to investigate the diagnostic performance.

Study description

Background summary

Bronchoscopy is one of the most important procedures in diagnosis of lung cancer and other pulmonary diseases. This procedures renders important anatomical information and subtle changes in the epithelium or vascularity of the bronchial tree are clues to guide the endoscopist in this procedure, especially in case of centrally located lung cancer. These subtle changes may influence the choice of treatment, site of biopsy and resectability of lung cancers when determining resection margins but also in case of multifocal premalignant disease. A recently published meta-analysis has shown diagnostic

superiority of autofluorescence bronchoscopy (AFB) over routine white light bronchoscopy (WLB).
Through technological improvement a new technique has become available in the form of high-definition (HD-) bronchoscopy. Current normal video white light bronchoscopy is the standard, and video-autofluorescence bronchoscopy is offered by specialised centers only.
The impact of this development with high-definition videobronchoscopy using a 1.1 megapixel chip on the diagnostic performance of bronchoscopy is however unkown.

Study objective

(1) Investigate diagnostic performance (sensitivity) of HD bronchoscopy, with or without surface enhancement or tone enhancement in comparison to standard WLB for detecting abnormalities of the tracheobronchial tree. Furthermore we aim to investigate determination of resection margins of (suspected) malignancies in the glottic and supraglottic area or centrally located lung cancer in comparison to (SAFE 3000) autofluorescence bronchoscopy in a high risk population with biopsies from all suspect lesions identified by either technique.
(2) When the sensitivity and specificity of HD videobronchoscopy in either mode in the abovementioned study is in the vicinity of the reported sensitivity and specificity of SAFE3000 dual mode videobronchoscopy we suggest to use the results of this study to perform a power analysis. With this information it may then be possible to design a new future study to compare sensitivity for detecting premalignant lesions in a high risk population in a prospective study.

Study design

(1) Prior to surgery by the ENT surgeon or cardiothoracic surgeon bronchoscopy will be performed by an experienced chest physician through a laryngeal mask under general anaesthesia.

Bronchoscopy will be performed in a standardized order using five different imaging modes. The order of the different modes will be randomized.
High-definition digital videos will be made from all procedures without in screen indications of date, time or reference to study site or patient identification. The five imaging modes used in this study are:
1. Standard white light videobronchoscopy (WLB)
2. High Definition (HD)-Bronchoscopy
3. HD-bronchoscopy + surface enhancement
4. HD-bronchoscopy + tone enhancement
5. Auto Fluorescence Bronchoscopy (AFB - SAFE3000) in dual video mode

All visible abnormalities suspected for malignancy or pre-malignancy will be

biopsied afterwards. The HD-digital video*s will be reviewed by the experienced bronchoscopists in random order and blinded for patient, study site and date and scored using a predefined scoring system to describe surface, vascularity and tumours. Premalignant lesions identified by multiple techniques are considered as non-inferior.

From each patient 5 HD- films will be generated. These films will be reviewed in a blinded fashion and random order by two experienced pulmonologists and an independent equally experienced third pulmonologist.
These videos will be scored on epithelial changes, vascularity changes, presence or suspicion of dysplasia, presence of suspicion of carcinoma in situ, and tumor margins.

When new clinically relevant abnormalities are found, the impact of these findings on the planned diagnostic or therapeutic procedure will be registered.

Study burden and risks

At the start of the general anaesthesia for the planned operation a laryngeal mask airway is inserted by the anesthesiologist.
Bronchoscopy is then performed by a very experienced pulmonologist using routine topical anesthetics. In this way the burden for the patient and the risk of complications is very low. These patients have an indication for the planned procedure and have been evaluated by an anesthesiologist prior to the procedure and are considered fit for surgery. The total anesthesia time for the planned procedure will be increased by 10 to 15 minutes.
Bronchoscopy is a very safe diagnostic procedure, the reported complications are in general attributable to te more invasive diagnostic procedures performed during that diagnostic bronchoscopy like biopsy, lavage and needle aspirations. This is not the aim of this study, invasive diagnostic procedures will only be performed in case of a clinically relevant new finding.
In general we expect that the vast majority of the patients involved will not have any benefit of participating in this study.

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

-Patients fit for surgery and scheduled for diagnostic or therapeutic surgical procedure under general anesthesia by the cardiothoracic or thoracic surgeon or ENT surgeon with suspected or proven lung cancer or ENT malignancy.
-ASA physical status 1-3.
-Age 18 years or older.

Exclusion criteria

Contraindications are all known contraindications for diagnostic bronchoscopy such as:
- bleeding disorders,
- indication for use of anticoagulant therapy (acenocoumarol, warfarine, therapeutic dose of low molecular weight heparines or clopidrogel),
- known allergy for lidocaine,
- known pulmonary hypertension,
- recent and/or uncontrolled cardiac disease.
Presence of contraindications for the use of laryngeal mask (anatomical abnormalities) increased risk for intubation (malampatti score 4),
ASA classification greater than or equal to 4.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-03-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	video bronchoscopy
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-05-2012
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

ID: 27818
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL38719.091.11
OMON	NL-OMON27818

Study results

Date completed: 01-03-2014

Actual enrolment: 29

Summary results
Trial is onging in other countries