Diagnostische waarde van hoge resolutie bronchoscopie in vergelijking met standaard video bronchoscopie en autofluorescentie bronchoscopie.

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

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

Samenvatting

ID

NL-OMON27818

Bron
Nationaal Trial Register

Aandoening

Diagnostic bronchoscopy
High Definition imaging
Lung Cancer
Head and Neck Cancer

Ondersteuning

Primaire sponsor: UMCN St. Radboud
Overige ondersteuning: UMCN St. Radboud

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

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 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). Furthermore, patients with a head and neck cancer have an increased risk of developing lung cancer given their smoking habits. 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 (AFB) is offered by specialized 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.

Objective (primary and secondary outcome):

(1) Investigate sensitivity of HD bronchoscopy, with or without surface enhancement or tone enhancement in comparison to AFB (the ‘gold standard’) and 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 autofluorescence bronchoscopy (SAFE 3000 dual video mode) 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 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:

This study is a descriptive exploratory randomized observational study with a blinded post procedure analysis of the diagnostic performance of HD bronchoscopy in comparison to WLB and AFB.

Study population:

Patients scheduled for diagnostic or therapeutic procedure under general anesthesia by the cardiothoracic or thoracic surgeon or ear-, nose- and throat (ENT) surgeon with suspected or proven lung cancer or head and neck cancer are eligible for this exploratory study. Eligible are patients with ASA physical status 1-3 patients aged 18 years or older. Ineligibility criteria are all known contraindications for diagnostic bronchoscopy (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 procedure:

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: Standard white light videobronchoscopy (WLB); High Definition (HD-) bronchoscopy; HD-bronchoscopy + surface enhancement; HD-bronchoscopy + tone enhancement and 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. When new clinically relevant abnormalities are found the normally indicated diagnostic procedures will be followed and performed immediately after completion of the videoregistration. All findings will be disclosed to the patient and the physician in charge by the investigator and the impact of these findings on the planned diagnostic or therapeutic procedure will be registered.

Main study parameter / endpoints:

The bronchoscopy videos will be scored by blinded experienced endoscopists on epithelial changes, vascularity changes, presence or suspicion of dysplasia, presence of suspicion of carcinoma in situ, and tumor margins. The study is a descriptive exploratory 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. As a secondary oucome we aim, when differences are established between the different bronchcopy modes, to perform a power analysis to determine the feasibility of a prospectively designed study to investigate the diagnostic performance of HD bronchoscopy.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

After 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 anesthesics. In this way the burden for the patient and the risk of complications is very low. These patients have an indication for the planned surgical 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.

Doel van het onderzoek

1. Investigate sensitivity of HD bronchoscopy, with or without surface enhancement or tone enhancement in comparison to AFB (the ‘gold standard’) and 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 autofluorescence bronchoscopy (SAFE 3000 dual video mode) 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 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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

After start of general anesthesia but prior to surgery by the ENT surgeon or cardiothoracic surgeon the 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 patient identification.

The five imaging modes used in this study are:

1. Standard white light videobronchoscopy (WLB);

2. High Definition -Bronchoscopy;

3. HD-bronchoscopy + surface enhancement (iScan-surface);

4. HD-bronchoscopy + tone enhancement (iScan-tone);

5. Auto Fluorescence Bronchoscopy (AFB - SAFE3000) in dual video mode.

All unforeseen newly discovered abnormalities suspected for malignancy or pre-malignancy will be biopsied following the normal clinical procedures after completion of the video recordings but during the same procedure under general anesthesia.

The HD-digital video’s will be reviewed by two involved experienced bronchoscopists in random order and blinded for patiënt ID and study date. A third equally experienced but not involved chest physician will also be asked to score all video’s. The images will be analysed using a predefined scoring system to describe surface, vascularity and tumour margins. In the event of premalignant lesions identified by multiple imaging techniques these imaging modes are considered as non-inferior.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 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 head and neck cancer;

2. ASA physical status 1-3;

3. Age 18 years or older;

4. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Contraindications are all known contraindications for diagnostic bronchoscopy such as:

1. Bleeding disorders;

2. Indication for use of anticoagulant therapy (acenocoumarol, warfarine, therapeutic dose of low molecular weight heparines or clopidrogel);

3. Known allergy for lidocaine;

4. Known pulmonary hypertension;

5. Recent and/or uncontrolled cardiac disease;

6. Presence of contraindications for the use of laryngeal mask (anatomical abnormalities);

7. Increased risk for intubation (malampatti score 4);

8. Compromised upper airway due to extension of primary head and neck cancer;

9. ASA classification greater than or equal to 4.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-07-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35123
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3374
NTR-old	NTR3522
CCMO	NL38719.091.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35123

Resultaten

Samenvatting resultaten
N/A