A multicenter study evaluating the diagnostic value for vascular abnormalities of High Definition Bronchoscopy when combined with i-scan Imaging Technology compared to High Defintion Bronchoscopy alone

Published: 02-10-2014
Last updated: 22-04-2024

Primary objective:Determing the positive predictive value and diagnostic yield of HD+ i-scan bronchoscopy for vascular pattern detection .Secondary objectives:1. To investigate the correlation of vascular abnormalities with histology2. To...

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

Summary

ID

NL-OMON40848

Source
ToetsingOnline

Brief title
i-scan multicenter study

Condition

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

Synonym
lungcancer

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, High definition imaging, histology, Lung cancer

Outcome measures

Primary outcome

Determing the positive predictive value and diagnostic yield of HD+ i-scan

bronchoscopy for vascular pattern detection compared to histology.

Secondary outcome

• To investigate the correlation of vascular abnormalities with histology

• To investigate the impact of i-scan technology on the clinical approach or

follow-up plan

• To investigate the interobserver variability

• Investigate diagnostic performance and determing the positive predictive

value of HD+ i-scan bronchoscopy in comparison to normal HD-WL on demarcation

of tumour margins

Study description

Background summary

Videobronchoscopy is an essential diagnostic procedure for evaluation of the central airways and pivotal for the diagnosis and staging of lung cancer. Through technological improvement new technique have become available in the form of high-definition (HD+) bronchoscopy. Furthermore, in combination with

improved video processor unit this HD bronchoscope offers post processing real time image enhancement (i-scan Technology) [Kodoshima WJG 2010]. Our earlier exploratory study showed that HD+bronchoscopy with i-scan detected significantly more sites with abnormal and suspicious vascular patterns [van der Heijden 2014- submitted]. The impact of this visual finding with high definition videobronchoscopy using a 1.1 megapixel chip on the diagnostic performance of bronchoscopy is however unknown since in this pilot study no biopsies were taken.
In this study we therefore aim to investigate the PPV and diagnostic yield of HD+ bronchoscopy, with or without surface enhancement or tone enhancement in comparison to biopsy outcome of all sites with abnormal and / or suspicious vascular patterns in patients with known or suspected lung cancer.

Study objective

Primary objective:
Determing the positive predictive value and diagnostic yield of HD+ i-scan bronchoscopy for vascular pattern detection .
Secondary objectives:
1. To investigate the correlation of vascular abnormalities with histology
2. To investigate the impact of i-scan technology on the clinical approach or follow-up plan
3. To investigate the interobserver variability
4. Investigate diagnostic performance and determing the positive predictive value of HD+ i-scan bronchoscopy in comparison to normal HD-WL on demarcation of tumour margins

Study design

The study is designed as a randomized controlled, cross-over, multi-centric investigator initiated study where each patient serves as its own control.
A total of 5 centers in Europe will participate with this study. We aim to start in October 2014 and complete inclusion to the study within one year, by October 2015.

Patients will undergo a bronchoscopy with Pentax EB1990i HD-bronchoscope in combination with Pentax EPKi series videoprocessor investigating the entire bronchial tree. Three modalities will be used: (1) HD+, (2) HD+ surface enhancement (SE, i-scan1) and (3) HD+ surface enhancement and tone enhancement (TE-c, i-scan2).
When sites with abnormal or suspicious vascular patterns are detected the investigator will change to a normal bronchoscope and take biopsies from each site and a biopsy from a normal secondary carina on the contralateral site as control. Changing of scopes is mandatory since the working channel of the EB1990i bronchoscope does not allow introduction of a biopsy forceps. Finally any other indicated procedures will be performed at the discretion of the local

investigator.
The local investigator will immediately complete the CRF identifying all locally identified and biopsied suspicious sites. Furthermore in the CRF will identify whether this study-bronchoscopy has altered the clinical workup or treatment of this patient and register any complications.
All videos will be analyzed centrally at RadboudUMC in random order, blinded for patient outcome and type of bronchoscopy, by two experienced investigators to determine interobserver variability.
All videos will be reviewed in joined reading at RadboudUMC with disclosure of the pathology outcome of biopsies taken by the local investigator to correlate visual scores to pathology and determine preferred modality.

Study burden and risks

The burden and risks associated with participation are considered low. Patients that will be approached for study participation have an indication for a bronchoscopy investigation. When they participate in this study the procedure will be performed more extensively with a dedicated HD+ bronchoscope followed by a bronchoscopy using a standard bronchoscope when tissue sampling is indicated. The entire procedure will take an additional 5-10 minutes to complete. However after inspection with the HD bronchoscope a regular bronchoscope is needed to obtain biopsies and perform the indicated other diagnostic procedures.
Bronchoscopy is a very safe diagnostic procedure, the reported complications are in general attributable to the more invasive diagnostic procedures performed during that diagnostic bronchoscopy like biopsy, lavage and needle aspirations. The chance of complications like bleeding and infection is low (< 1%).
In general we expect that the majority of the patients involved will not have a clinical relevant benefit of participating in this study other than that the bronchoscopy will always be performed by very experienced bronchoscopist.

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 with indication for diagnostic bronchoscopy for suspected or proven lung cancer.
-ASA physical status 1-3.
-Age 18 years or older.

Exclusion criteria

-Bleeding disorders.
-Indication for use of anticoagulant therapy (acenocoumarol, warfarin, therapeutic dose of low molecular weight heparines or clopidrogel).
-Known allergy for lidocaine.
-Known pulmonary hypertension.
-Recent and/or uncontrolled cardiac disease.
-Compromised upper airway (eg concomitant head and neck cancer or central airway stenosis for any reason).
-ASA classification greater than or equal to 4.
-Pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-10-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	02-10-2014
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	NL50121.091.14