Safety and efficacy of a flexible endobronchial sampling instrument that obtains a CORe sample from KeY suspected areas of pulmonary and mediastinal lesions.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract neoplasms
Study type	Interventional

Summary

ID

NL-OMON56672

Source
ToetsingOnline

Brief title
COReKeY

Condition

- Respiratory tract neoplasms

Synonym
lung cancer, suspicious peripheral pulmonary lesions

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Lung cancer diagnostics, Navigation bronchoscopy, Peripheral pulmonary lesions, Sampling tools

Outcome measures

Primary outcome

The primary objective of this safety and efficacy study is to assess the overall diagnostic yield. Diagnostic yield is defined as the number of times the procedure was diagnostic (either malignant or benign), relative to the total number of attempted navigation procedures. The criteria for what constitutes a diagnostic sample will be modelled after the strict definitions as proposed by Vachani et al. (Vachani et al. Chest, 2020). When applying this definition, a diagnosis can only be determined based on pathology results from the study procedure and without follow-up information. Diagnostic outcomes are malignant or specific benign diagnoses (e.g., granulomatous inflammation, fungal infection). All other findings are categorized as non-diagnostic. This definition allows for a conservative analysis of the outcomes, and has strong clinical applicability.

Secondary outcome

The secondary objective of this study is to assess safety. The most common complication that can be expected are pneumothorax (with or without requiring chest tube drainage) and bleeding.

Bleeding will be classified according to standardized definitions proposed by

folch et al. (Folch et al. Chest, 2020)

Other secundary outcomes are

- Position confirmation of the instrument confirmed by cone-beam CT (CBCT)

- Biopsy instrument characteristics, primarily: biopsy duration per sampling

strategy and the number of biopsies taken

- Ease of use of the research tool

- The pathology outcome of tissue samples analyzed during rapid onsite

evaluation (ROSE)

- Suitability of the obtained tissue for any subsequent full molecular

analysis.

Study description

Background summary

Early diagnosis of lung cancer can improve treatment options and consequently improve survival and prognosis. Navigation bronchoscopy (NB) is a minimal invasive diagnostic procedure with a low complication rate and a relatively high diagnostic yield. It uses a flexible bronchoscope in combination with extended working catheters and imaging techniques to accurately reach and sample small peripheral pulmonary nodules. Using NB we are able to accurately reach the lesion in ± 90% of all cases, but despite that, the average diagnostic yield is approximately 75% (Kops et al., Lung Cancer 2023). This discrepancy between getting there and obtaining a diagnosis might be explained by the manner in which we sample the lesion. The biopsy techniques currently in use are fine needle aspiration, forceps biopsy and cryobiopsy. These tools are used in combination with one another, and multiple samples per tool are taken in routine clinical practice as they do not allow a tru-cut sample from the suspected lesion in a single go. Due to motion as a consequence of tool in catheter insertion, lesion stiffness, breathing and or intermittent catheter movement in-between samples, repeated sampling is required. The discrepancy between getting there and getting a diagnosis in even the most recent literature shows there is considerable margin of error. There seems to be high demand for a sampling tool which might bridge this gap between navigation success and an accurate diagnostic outcome. The COReKEY investigational device

(hereafter named Investigational Device) is a new biopsy instrument that provides a cross-sectional sample of the nodule. The design is based on the spirotome technique, which is widely implemented and the preferred sampling tool in other forms of biopsy, such as CT guided transthoracic biopsy (TTNB), a procedure with a high diagnostic yield of approximately 90% [1]. This new sampling tool only needs 1 or 2 samples to obtain a core biopsy of the suspected lesion and can potentially increase the diagnostic yield of the navigation bronchoscopy procedure. This clinical feasibility study aims to assess the safety and efficacy of the Investigational Device in the navigation bronchoscopy procedure compared to the conventional sampling strategy

Study objective

The primary objective of this clinical feasibility study is to assess the overall diagnostic yield of the Investigational Device in comparison to standard care. The secondary objective is to assess the safety issues that possibly occur while using the Investigational Device. Other secondary objectives include the assessment of tool-in-lesion confirmation of the Investigational Device on cone-beam CT (CBCT) as compared to conventional sampling tools, sampling tool characteristics (duration and counts), ease-of-use of the Investigational Device during tissue sampling, pathology outcome of samples analysed during rapid onsite evaluation (ROSE), and if sufficient tissue is present for later full molecular analysis.

Study design

This is a prospective, single-center, interventional feasibility study at the Radboud UMC in Nijmegen. The safety and efficacy of the Investigational Device in the navigation bronchoscopy procedure as performed per routine clinical practice will be assessed.

Intervention

The navigation bronchoscopy procedure consists of three phases: (1) navigation, (2) confirmation of the correct position and (3) tissue acquisition of the pulmonary nodule. The navigation and confirmation phases are performed according to standard practice, with the Investigational Device being used only during the tissue acquisition phase. All included patients will undergo sampling with both conventional tools (conventional sampling strategy) and the Investigational Device (Investigational Device Strategy). The conventional sampling strategy will be standardized for optimized comparison: For every patient, 3 samples with transbronchial needle (TBNA) will be taken, followed by a minimum of 3 samples with forceps. If these samples do not provided a preliminary diagnosis suspicious of malignancy, as determined by rapid onsite evaluation (ROSE), additional cryobiopsy sampling will be obtained. Samples will be collected in separate containers per sampling tool. This will allow

diagnostic yield comparison between different sampling strategies, while maintaining standard practice quality of care. The Investigation Device strategy will include sampling with the investigational device at least once, as per manufacturer*s instructions by *screwing* the tool into place and sliding over the secondary cutting cannula to extract the sampling tissue from the peripheral pulmonary lesion.

Patients will be randomized for sampling order. 1) sampling with the Investigational Device first followed by conventional tools. 2) sampling with conventional tools first followed by the Investigational Device. This will minimize the bias that previous sampling might have on subsequent sampling (e.g. because of limited bleeding around the lesion obscuring vision on image guidance). The obtained samples (both conventional and Investigational Device samples) are analyzed for ROSE and pathological assessment.

Study burden and risks

The expected potential risks of including the Investigational Device in the navigation bronchoscopy procedure are low. During the conventional NB procedure, a pneumothorax and/or a bleeding may occur. The pneumothorax rate during the conventional NB procedure in the Radboudumc was 2.6%, while the incidence of bleeding was 1.0% based on all performed procedures between July 2020 and december 2021 (Kops et al. 2023, submitted). During this clinical study the currently used sampling tools will be compared with the Investigational Device in an intrapatient analysis, which means that per patient both sampling techniques will be used. This could potentially increase the amount of complications, because more samples are taken from the lung nodule. The complication rates should, however, not increase by 5% in this investigation study when compared to our previous findings.

The expected benefit from the Investigational Device is the increase in diagnostic accuracy because a cross-sectional sample is provided by the Investigational Device instead of a small area of the nodule.

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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 with an indication for cone-beam CT guided navigation bronchoscopy for the diagnosis of a peripheral pulmonary nodule are eligible for study inclusion.

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- ASA physical status 1-3
- Age above 18 years
- A single pulmonary nodule with an indication for diagnostic evaluation following current clinical guidelines
- Subject is willing and able to give written informed consent for clinical investigation participation prior to the procedure

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- Contra-indication for navigation bronchoscopy
- Not fit to undergo navigation bronchoscopy
- Patient is pregnant
- Inability to consent

- Less than 18 years old
- Contra-indication for temporary interruption of the use of anticoagulant therapy (acenocoumarin, warfarin, therapeutic dose of low molecular weight heparins, clopidogrel or analogs, NOAC*s)
- Uncontrolled pulmonary hypertension
- Recent and/or uncontrolled cardiac disease
- Compromised upper airway (e.g., central airway stenosis for any reason such that endobronchial access is considered unsafe)
- Patient is involved in another pulmonary intervention study
- Indication for minimal invasive biopsy of multiple nodules in one procedure
- Endobronchial visible tumor

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-07-2024
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Spirotome flex
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-03-2024
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	NL84502.091.23