A Prospective Investigation to Assess the Diagnostic Yield of using a Robotic Navigational Bronchoscopy System with Adjunct Real-time Imaging

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The primary objective of this Clinical Investigation is to evaluate the diagnostic yield using the Ion Endoluminal System when used with adjunctive 3D imaging modalities for the biopsy of peripheral pulmonary nodules (PPNs). In a first phase, the...

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

Summary

ID

NL-OMON56343

Source
ToetsingOnline

Brief title
Diagnostic yield with Robotic Navigational Bronchoscopy System and CBCT

Condition

- Respiratory tract neoplasms

Synonym
lung nodule identified on a CT scan which requires a biopsy procedure., Patients with a moderate to high risk of lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Intuitive Surgical, Inc.
Source(s) of monetary or material Support: Intuitive Surgical;Inc.

Intervention

Keyword: Biopsy, Bronchoscopy, Navigational, Nodule

Outcome measures

Primary outcome

Primary performance endpoint:

- Diagnostic yield of sample(s) obtained (post learning curve)

- Sensitivity CUSUM analysis (learning curve)

Secondary outcome

Secondary performance endpoint:

- Sensitivity for malignancy of sample(s) obtained

- Rate of achieving biopsy tool position within the targeted nodule(s) as

confirmed by CBCT 3D imaging or the combination of multi-angle augmented

fluoroscopy with rEBUS and diagnostic rapid onsite pathology (in the absence of

a confirmatory spin).

Safety endpoint:

- Rate of procedure-related Adverse Events through 7 days post-procedure

Exploratory endpoint:

- Procedure-related characteristics:

o Total number of imaging spins to obtain Tool in Nodule(s) as defined above

o Number of catheter readjustments required to obtain Tool in Nodule(s)

o Tool to nodule spatial relationship

o Duration-related outcomes:

- procedure time (from catheter inserted into the patient*s airways to

catheter removed from the patient*s airways)

- navigation time

- time to rEBUS visualization

- biopsy time

o Number of additional interventional diagnostic procedures required post-

procedure for a definitive diagnosis of the target nodule(s)

o rEBUS visualization characteristics

o Biopsy workflow, including but not limited to, sequence of biopsy tools used

Study description

Background summary

According to 2020 estimates by the International Agency for Research on Cancer and World Health Organization, the incidence of lung cancer worldwide represents 11.4% of all cancers diagnosed, and the mortality rate due to lung cancer was as high as 18% of all cancer-related deaths. Besides the aggressive nature of lung cancer, its high mortality is mainly attributed to the delay between symptom presentation and cancer progression. Late detection of lung cancer can cause the pulmonary nodule to continue to grow and spread to other parts of the lung, leading to potential metastasis to other parts of the body before any symptoms are observed. Therefore, rapid identification of pulmonary nodules is a critical challenge that needs to be addressed for early diagnosis of lung cancer. Despite the development of guided-bronchoscopy including virtual bronchoscopy, and electromagnetic navigation, the diagnostic yield remains lower than that of image guided transthoracic needle aspiration [13]. The study device, through its uniquely designed catheter with shape-sensing technology and small outer diameter, can reach peripheral airways to provide the physician the ability to potentially improve biopsy sampling for small

nodules. This Clinical Investigation was designed to evaluate the learning curve and diagnostic yield of using the Ion Endoluminal System when used with adjunctive 3D imaging modalities for biopsy of peripheral pulmonary nodule(s) and to evaluate the rate of Tool in Nodule(s), the procedural characteristics and diagnostic characteristics of the sample obtained by the Ion Endoluminal System.

[13] Agrawal, A., D.K. Hogarth, and S. Murgu, Robotic bronchoscopy for pulmonary lesions: a review of existing technologies and clinical data. J Thorac Dis, 2020. 12(6): p. 3279- 3286.

Study objective

The primary objective of this Clinical Investigation is to evaluate the diagnostic yield using the Ion Endoluminal System when used with adjunctive 3D imaging modalities for the biopsy of peripheral pulmonary nodules (PPNs).
In a first phase, the learning curve of the procedure will be retrospectively assessed using CUSUM analysis. In a second phase (after having concluded that the initial learning curve has passed), the diagnostic characteristics (e.g. diagnostic yield and accuracy) is further evaluated through a prospective pilot study. The included patients and lesions are propensity score matched to an available database of CBCT-guided navigation bronchoscopy procedures as routinely performed in the Radboudumc for comparison.

The secondary objective of this Clinical Investigation is to evaluate procedural characteristics and diagnostic characteristics of the sample(s) obtained by the Ion Endoluminal System.

Study design

A prospective, dual-arm, interventional study.
Prospective collection of consecutive patients undergoing a biopsy procedure with the Ion Endoluminal system with CBCT imaging, and comparing these results with the prospectively collected cohort of CBCT-navigation bronchoscopy procedures performed at Radboudumc.

Intervention

Patients with peripheral pulmonary nodule(s) measuring >=6 mm and <=3 cm in largest dimension (based on pre-procedure CT scan) who are indicated to undergo bronchoscopic biopsy for lung nodule(s) of unknown etiology, suspicious for primary lung cancer or metastatic disease will undergo Robotic Navigational Bronchoscopy.

Study burden and risks

Risk management activities reduced the degree of potential risks through risk control measures for the study device, but residual risks remained (Investigator*s Brochure). A range of adverse events could occur depending upon the severity of the injury and the timing of its identification. The harms related to the study device range from no adverse health consequences up to and including critical, related to pneumothorax requiring intervention, biocompatibility/cytotoxic response, infection, procedural delays and toxic reaction from foreign body. The probability of severe adverse events is extremely low given the multiple mitigations. Various high-residual-risk items for the study device have been described in terms of likelihood and severity of adverse events, such as pneumothorax and bleeding. Refer to the investigator brochure for the complete list of foreseeable adverse device events.
In light of the potential clinical benefits, and measures for risk mitigation, we conclude that the benefits of lung biopsy using the investigational study device outweigh the potential risks. Refer to the Investigator*s Brochure for comprehensive list for risk mitigation.

Risks associated with bronchoscopic lung biopsy procedures under general anesthesia are usually minor and transient. Also, serious adverse events may occur. There may also be risks associated with the use of general anesthesia or an endotracheal tube, which are not specific to the investigational procedure.

For the risks and benefits of the investigational device, clinical procedure and clinical investigation refer to chapter 5 of the CIP.

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

1. Patient is aged 18 years or older at time of consent.
2. Patient is suitable for elective nodule biopsy via bronchoscopy under general anesthesia per Investigator*s discretion.
3. Patient has solid or semi-solid pulmonary nodule(s) of >=6 mm and <=3 cm in largest dimension (based on pre-procedure CT scan).
4. Pulmonary nodule(s) intended for biopsy during the study procedure is (are) located at least 4 (>=4) airway generations out (trachea = generation 0, e.g. subsegmental bronchi or beyond) based on pre-procedure CT scan.
5. Patient has a moderate to high risk of lung cancer based on clinical, demographic, and radiologic information or with suspected metastatic disease. High risk for malignancy patients are eligible if a biopsy is required or requested prior to intervention.
6. Patient is willing and able to give written informed consent for Clinical Investigation participation.
7. Patient is not legally incapacitated or in a legal/court ordered institution.

Exclusion criteria

1. Patient has a lack of fitness or exercise capacity to undergo bronchoscopy under general anesthesia as determined by Investigator prior to procedure.
2. Patient with type 1 pure ground glass opacity target nodule(s) for biopsy during study procedure.
3. Presence of bullae(s) with a size of > 1 cm on pre-procedure CT scan located in close proximity to target nodule(s) and near the planned trajectory of the biopsy instruments.
4. Presence of mediastinal nodal disease on pre-procedure CT or PET-CT scan.
5. Patient with ASA >=4.
6. Patient underwent a pneumonectomy.
7. Any invasive concomitant procedure (outside of lymph node staging) not related to the pulmonary nodule(s) or suspected disease state.

8. Female patient of child-bearing potential who is unable to take adequate contraceptive precautions or is known to be pregnant, and/or breast feeding.
9. Patient has a documented medical history of uncorrectable coagulopathy, bleeding, or platelet disorder.
10. Patient is taking antiplatelet or anticoagulant medications that cannot be stopped per standard practice.
11. Patient is currently participating or has participated in another Clinical Investigation within the past 30 days, such as interventional trials or trials with experimental agents or agents of unknown risk, that may affect the endpoints of this Clinical Investigation.
12. Investigator, in their professional opinion, has decided that it is in the patient*s best interest to not participate in the Clinical Investigation.
13. Patient is not willing to comply with post study procedure participation requirements.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2023
Enrollment:	131
Type:	Actual

Medical products/devices used

Generic name:	Ion Endoluminal System;Instruments;and Accessories
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-09-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-06-2024
Application type:	Amendment
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	NL79689.091.23