Immunological profiling of hilar and mediastinal lymph nodes in lung cancer patients

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We aim to explore the feasibility of immunological cell typing of endobronchial ultrasound (EBUS) guided fine needle aspirates (FNA) of lymph nodes and to develop immunodynamic biomarkers during SABR treatment.

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

Summary

ID

NL-OMON41899

Source
ToetsingOnline

Brief title
Immunological profiling of lymph nodes in NSCLC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
lung cancer, pulmonary malignancy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: EBUS, NSCLC, Tumor immunology

Outcome measures

Primary outcome

For the exploration part: difference in the percentage and ratio of immune cells between tumor draining lymph nodes (TDLNs), non-tumor draining lymph nodes (NTDLNs), bronchial wash and peripheral blood. For the qualification part: change in the percentage, activation status and ratio of selected immune cells in TDLNs and NTDLNs after SABR treatment as compared to baseline.

Secondary outcome

not applicable

Study description

Background summary

A recent matched cohort analysis showed a higher locoregional control rate for stereotactic ablative radiotherapy (SABR) as compared to video-assisted thoracoscopic (VATS) lobectomy for early stage non-small-cell lung cancer (NSCLC) with a trend towards better overall survival. The unexpected difference in locoregional recurrence may be related to an immunological response. We hypothesize that, in addition to the tumor itself, the draining lymph nodes of the primary tumor are the most relevant location to search for the presence of immunomodulation.

Study objective

We aim to explore the feasibility of immunological cell typing of endobronchial ultrasound (EBUS) guided fine needle aspirates (FNA) of lymph nodes and to develop immunodynamic biomarkers during SABR treatment.

Study design

Pilot exploratory study with biomarker exploration, followed by biomarker

qualification.

During the exploration and validation step 10 patients will undergo an endoscopy as part of their regular diagnostic workup. EBUS-FNA of the lymph nodes and a bronchial wash will be performed and blood drawn to compare the distribution of immune effector cell subsets between blood, tumor and lymph nodes and to identify the most interesting and feasible cell subsets to focus on for the qualification phase. During the qualification step 10 patients will undergo an endoscopy before and after SABR treatment to identify changes in the immune effector cell subsets.

Study burden and risks

The burden and risks associated with participation are considered low. Bronchoscopy with ultrasound is used in daily practice and is not associated with significant complications. Patients who will be approached for study participation already have an indication for a pretreatment EBUS procedure. The posttreatment endoscopy after SABR in the qualification phase of this study is however not part of regular care and is performed for the purpose of 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

* Be willing and able to provide written informed consent for the study.
* Be 18 years of age or older on the day of signing informed consent.
* A (suspected) diagnosis of NSCLC.
* For the exploration and validation part TNM stage cTxN1-2Mx.
* For the qualification part TNM stage cT1-2aN0M0 and planned for SABR treatment.
* At least one lymph node with a minimal short axis diameter of 10 mm.
* Eligible to undergo an EBUS procedure according to the treating physician and international guidelines.
* Able to undergo an EBUS procedure according to institutional guidelines.

Exclusion criteria

* Active infection requiring systemic therapy.
* A diagnosis of immunodeficiency or is receiving systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior to the first dose of trial treatment.
* A known additional malignancy that is progressing or requires active treatment. Exceptions include basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or in situ cervical cancer that has undergone potentially curative therapy.
* Major surgery or blood transfusions in the past 3 months.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-05-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	04-03-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL50035.029.14