Longitudinal analysis of lung cancer-specific immunity in stage III and IV non-small cell lung cancer patients

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• To study the effect of treatment modalities immunotherapy (anti-PD1 or anti-PDL-1), and targeted therapy (crizotinib, gefitinib or erlotinib) on the size and diversity of lung carcinoma-specific T cell populations as measured by immune assays,...

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

Summary

ID

NL-OMON37300

Source
ToetsingOnline

Brief title
Longitudinal analysis of non-small cell lung cancer-specific immunity

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
non-small cell lung cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Non-small cell lung cancer, Peripheral blood samples, T-cell immunity, Tumor biopsies

Outcome measures

Primary outcome

The longitudinal effects of treatment for irresectable stage III or IV

non-small cell lung cancer on tumor material obtained by surgical

removal/biopsies and on peripheral blood components.

Secondary outcome

Not applicable.

Study description

Background summary

There is evidence that tumor-specific T cell responses can contribute to the control of lung carcinoma. However, there is little known about the longitudinal development of lungcarcinoma-specific T cell immunity upon immunotherapeutic treatment. Better knowledge on the development of non-small cell lung carcinoma-specific T cell responses both in peripheral blood and at the tumor site is likely to offer leads for early monitoring of treatment response and for the development of more targeted immunotherapies. Furthermore, it has been postulated that also other therapeutic strategies that have been developed or are currently used in NSCLC potentially exert ther effect in part through the induction of a lung carinoma-specific T cell response. In this concept chemotherapy or targeted therapy might act to *prime* the immune response, whereas immune checkpoint blockade such as anti-CTLA-4 or anti PD1 acts to *boost* it by augmenting the immune response. At present, no data are available on the relationship between treatment of lung carcinoma with these types of drugs and the development of tumor-specific T cell responses, either in peripheral blood or at the tumor site.

Study objective

• To study the effect of treatment modalities immunotherapy (anti-PD1 or anti-PDL-1), and targeted therapy (crizotinib, gefitinib or erlotinib) on the

size and diversity of lung carcinoma-specific T cell populations as measured by immune assays, including MHC tetramer technology and antigen-specific cytokine production.
• To examine effect of the treatment modalities immunotherapy (e.g. anti-PD1, anti-PDL-1), and targeted therapy (e.g. crizotinib, gefitinib) on the immune infiltrates present within biopsies.
• To examine the repertoire of potential T cell antigens in NSCLC lesions by genomic analysis.

Study design

Longitudinal analysis: 50 patients were asked to provide blood and tumor tissue to allow further translational research in the laboratory.

Study burden and risks

The downside of participation in this study is that there will be more blood taken than normal. There will be also at least 2 tumor biopsies taken, what possibly can give an infection, hemorrhage, bruising or other discomfort, like fair feeling. The blood tests and tumor biopsies will be combined as far as possible with the regular visits to the clinic, so that the patient shouldn't come specially to the hospital.

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

• Histologically or cytologically proven irresectable stage III or IV non-small cell lung cancer
• Age above 18 years
• Performance score: WHO 0, 1 or 2 at the time of study entry
• Written informed consent
• Specific inclusion criteria for tissue biopsies:
- Only target lesion with limited biopsy-procedure related complication risk will be sampled; For instance easily accessible peripheral lymph nodes, subcutaneous, pleural, liver metastastasis.
- Other lesions will only be included if there is a clinical necessity for tissue analysis (e.g. molecular profiling, resection metastasis in case of oligometastastic disease).
- Only non-irradiated lesions will be sampled

Exclusion criteria

• Severe anemia (Hb < 6.0 mmol/L)
• Any bleeding disorder or anti-coagulation therapy, that cannot be discontinued or corrected, that significantly increases the risk of a bleeding due to the biopsy.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Date:	21-12-2012
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25535
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41664.031.12
OMON	NL-OMON25535