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

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON25535

**Source**
Nationaal Trial Register

**Brief title**
Translational research

**Health condition**

Histologically or cytologically proven irresectable stage III or IV non-small cell lung cancer

### Sponsors and support

**Primary sponsor:** Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis
Amsterdam, The Netherlands
**Source(s) of monetary or material Support:** Self-financing research

### Intervention

### Outcome measures

**Primary outcome**

The longiutudinal 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

N/A

## 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 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 veen developed or are currently used in NSCLC potentially exert their effect in part through the induction of a lung carcinoma-specific T cell response. In this concept chemotherapy or targeted therapy micht 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 relationschip between treatment of lung carcinoma with these types of drugs and teh development of tumor-specific T cell responses, either in peripheral blood or at the tumor site.

### Study objective

1. 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;

2. 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;

3. To examine the repertoire of potential T cell antigens in NSCLC lesions by genomic analysis.

### Study design

Blood sampling will be done prior start of treatment (50ml), at the moment of first response evaluation (100ml), followed by 3 monthly sampling (50ml) , ≤ 3 drawings in total.

From patients who receive this type of treatments, a biopsy (optional) will be taken prior start

of treatment, 1-2 weeks after start of treatment and at the time of proven disease progression, in order to study the presence of new genetic mutations that lead to resistance to these targeted agents.

**Intervention**

Tumorbiopsies and peripheral blood samples.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Histologically or cytologically proven irresectable stage III or IV non-small cell lung cancer;

2. Age above 18 years;

3. Performance score: WHO 0, 1 or 2 at the time of study entry;

4. Written informed consent;

5. Specific inclusion criteria for tissue biopsies:

A. Only target lesion with limited biopsy-procedure related complication risk will be sampled; For instance easily accessible peripheral lymph nodes, subcutaneous, pleural, liver

metastastasis;

B. 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);

C. Only non-irradiated lesions will be sampled.

### Exclusion criteria

1. Severe anemia (Hb < 6.0 mmol/L);

2. 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

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|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 18-01-2013 |
| Enrollment: | 50 |
| Type: | Anticipated |

## Ethics review

Positive opinion

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|---|---|
| Date: | 11-02-2013 |
| Application type: | First submission |

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 37300
Bron: ToetsingOnline
Titel:

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

No registrations found.

## In other registers

| Register | ID |
|---|---|
| NTR-new | NL3674 |
| NTR-old | NTR3844 |
| CCMO | NL41664.031.12 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |
| OMON | NL-OMON37300 |

# Study results

**Summary results**
N/A