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

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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,...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25535

Bron
Nationaal Trial Register

Verkorte titel
Translational research

Aandoening

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

Ondersteuning

Primaire sponsor: Stichting Het Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis
Amsterdam, The Netherlands
Overige ondersteuning: Self-financing research

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Tumorbiopsies and peripheral blood samples.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	18-01-2013
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-02-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37300
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A