CA209-762: Fine needle aspiration (EUS/EBUS) versus histology for PD-L1 staining in lung cancer

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Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21496

Bron
Nationaal Trial Register

Verkorte titel
FNA versus histology

Aandoening

Non-small cell lungcancer (NSCLC)
Niet-kleincellig longkanker

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Groningen
Overige ondersteuning: Bristol-Myers Squibb

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Explore the agreement between cytology blocks and histology tissue, both stained for the presence of PD-L1.

Toelichting onderzoek

Achtergrond van het onderzoek

PD-L1 status is determined on histological specimen only. No data on PD-L1 staining are available for cytology specimen obtained by EUS/EBUS. Lung cancer tumors are often centrally located and diagnosis is most easily obtained by EUS/EBUS cytology. These diagnostic procedures show very little complications as opposed to histological procedures like CT guided core biopsies, peripheral bronchial biopsies or core biopsies from metastatic sides such as the liver. Therefore, we would like to explore whether PD-L1 status from tumor tissue by fine needle aspiration is comparable to a routine histological biopsy in these patients. To evaluate the clinical relevance, we would like to explore which patients with PD-L1 expression as assessed by fine needle aspiration are good responders on the treatment with PD-(L)1 inhibitors.

Country of recruitment: Netherlands

Doel van het onderzoek

PD-L1 is up to now the only marker that has been validated for the selection of patients treated for non-small cell lung cancer who might benefit from the treatment with PD-1/PD-L1 inhibitors. Thus far, PD-L1 status is assessed with histology, being an invasive technique. The value of cytology to assess PD-L1 status, being less invasive, is not known.

Onderzoeksopzet

At baseline, before receiving nivolumab.

Onderzoeksproduct en/of interventie

Both a fine needle specimen and a histological tumor biopsy will be obtained.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically confirmed stage IIIB and stage IV NSCLC

2. Smokers or ex-smokers with at least 15 Pack Years.

3. The tumor tissue sample must be fresh, preferably fresh frozen, in addition to routine FFPE-tissue processing from the primary tumor, core needle biopsy, excisional or incisional biopsies are accepted. Fine needle biopsies and drainage of pleural effusions with cytospins are not considered adequate as primary tumor biopsy sample.

4. Cytology will be obtained by either esophageal ultrasound (EUS), endobronchial ultrasound (EBUS) or ECHO guided fine needle aspiration of the same lesion that histology was obtained (preferably the primary tumor) and of a lymph node metastasis. Cytology will be obtained by rapid onsite cytology (ROSE), to ascertain sufficient tumour cells as assessed by an experienced laboratory technician.

5. Prior palliative radiotherapy must have been completed at least 2 weeks prior to first dose nivolumab.

6. Any line of previous chemotherapy.

7. At least one unidimensionally measurable lesion according to RECIST1.1 criteria.

8. Life expectancy more than 3 months.

9. ECOG PS 0/1.

10. Age 18 years and older, both male and female subjects.

11. Adequate organ functions.

12. Signed informed consent.

13. Male and female patients with reproductive potential must use an approved contraceptive method.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous treatment with PD-1 or PD-L1 inhibitor.

2. Pregnant or lactating women.

3. Patients who are poor medical risks because of non-malignant disease as well as those with active uncontrolled infection.

4. Patients without plasma sample at baseline (before treatment).

5. Patients are excluded if they have active brain metastases or leptomeningeal metastases. Subjects with brain metastases are eligible if metastases have been treated and there is no magnetic resonance imaging (MRI) evidence of progression for at least 4 weeks after treatment is complete and within 28 days prior to the first dose of nivolumab administration. There must also be no requirement for immunosuppressive doses of systemic corticosteroids (> 10 mg/day prednisone equivalents) for at least 2 weeks prior to study drug administration.

6. Patients receiving palliative radiotherapy to the primary tumor will be excluded.

7. Subjects with carcinomatous meningitis.

8. Subjects must have recovered from the effects of major surgery or significant traumatic injury at least 14 days before randomization.

9. Subjects with previous malignancies (except non-melanoma skin cancers, and the following in situ cancers: bladder, gastric, colon, cervical/dysplasia, melanoma, or breast) are excluded unless a complete remission was achieved at least 2 years prior to study entry and no additional therapy is required or anticipated to be required during the study period.

10. Other active malignancy requiring concurrent intervention.

11. Subjects with an active, known or suspected autoimmune disease. Subjects with type I diabetes mellitus, hypothyroidism only requiring hormone replacement, skin disorders (such as vitiligo, psoriasis, or alopecia) not requiring systemic treatment, or conditions not expected to recur in the absence of an external trigger are permitted to enroll.

12. Subjects with a condition requiring systemic treatment with either corticosteroids (>10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of randomization. Inhaled or topical steroids, and adrenal replacement steroid doses > 10 mg daily prednisone equivalent, are permitted in the absence of active autoimmune disease.

13. Subjects with interstitial lung disease that is symptomatic or may interfere with the detection or management of suspected drug-related pulmonary toxicity.

14. Known history of testing positive for human immunodeficiency virus (HIV) or known acquired immunodeficiency syndrome (AIDS).

15. Any positive test for hepatitis B virus or hepatitis C virus indicating acute or chronic infection.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-02-2017
Aantal proefpersonen:	40
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6070
NTR-old	NTR6217
Ander register	Bristol-Myers Squibb // METc UMCG : CA209-762 // 201600965

Resultaten