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

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21496

Source
NTR

Brief title
FNA versus histology

Health condition

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

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Bristol-Myers Squibb

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Explore for which patients with PD-L1 expression, the treatment with PD-1/PD-L1 inhibitors will lead to a durable response. A durable response is defined by having clinical benefit from a PD-(L)1 inhibitor for at least one year of treatment. For that, the included patients being treated with PD-(L)1 inhibitors, will be divided into two groups (those with durable response versus those without durable response).

Study description

Background summary

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

Study objective

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.

Study design

At baseline, before receiving nivolumab.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-02-2017
Enrollment:	40
Type:	Unknown

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL6070
NTR-old	NTR6217
Other	Bristol-Myers Squibb // METc UMCG : CA209-762 // 201600965

Study results