A Retrospective Evaluation of PD-L1 expression on primary non-small cell lung cancer samples and associated involved hilar or mediastinal lymph nodes (N1 or N2) (REPLICA)

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Study | Planned

Administrative details

PURI
https://redirect.ema.europa.eu/resource/26468

EU PAS number
EUPAS26467

Study ID
26468

DARWIN EU® study
No

Study countries
United Kingdom

Study description
The aim of this study is to evaluate whether there is heterogeneity of PD-L1 expression, between the primary NSCLC tumours and the associated hilar/ mediastinal lymph nodes (LNs) from the same patient at the time of lung resection.Samples (primary tumour and hilar/mediastinal LNs, N1 or N2) from 500 consecutive chemotherapy naïve patients who have undergone lung resection and hilar/ mediastinal lymphadenectomy for NSCLC (squamous and non-squamous cell cancer) without primary systemic treatment or Radiotherapy have been collected and will be analysed for PD-L1 expression. All tissue

samples will be anonymized.

Study status
Planned

Research institution and networks

Institutions

Guy's and St Thomas' NHS Foundation Trust
First published: 01/02/2024
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Institution

Birmingham University Hospital Birmingham, UK

Contact details

Study institution contact
Eleni Karapanagioutou
Study contact

Eleni.Karapanagiotou@gstt.nhs.uk
Primary lead investigator
Eleni Karapanagioutou
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
04/09/2018

Study start date
Planned:
30/10/2018

Date of final study report
Planned:
31/07/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD

Study protocol

REPLICA protocol v1.0 19Jan2018.pdf(702.7 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Methodological aspects

Study type

Study type list

Study type:
Non-interventional study

Scope of the study:
Disease epidemiology

Main study objective:

To analyse the correlation of PD-L1 expression in the primary site (lung) and associated hilar/mediastinal LNs (N1 and N2) in NSCLC looking at all variables in both primary tumour and hilar/ mediastinal LN.

Study Design

Non-interventional study design
Other

Non-interventional study design, other
Retrospective Observational Study with no medicinal product involvement

Study drug and medical condition

Medical condition to be studied
Non-small cell lung cancer metastatic

Population studied

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Estimated number of subjects
500

Study design details

Outcomes
To analyse the correlation of PD-L1 expression in the primary site (lung) and associated hilar/mediastinal LNs (N1 and N2) in NSCLC looking at all variables in both primary tumour and hilar/ mediastinal LN. Correlate the PD-L1 expression with:HistologyTumour sizetumour locationPredominant adenocarcinoma subtypeLymphovascular invasionClinical characteristicsagesexsmoking historyPET SUV data if available

Data analysis plan
Samples (primary tumour and hilar/mediastinal LNs) from 500 patients who underwent lung resection and hilar and/or mediastinal lymphadenectomy for NSCLC (squamous and non-

squamous cell cancer) without primary systemic treatment or Radiotherapy will be collected and analysed for PD-L1 expression.Expression of PD-L1 will be analysed on tumour samples in both primary tumours and hilar/ mediastinal LNs using the 22C3 pharmdx DAKO assay (5). The selected blocks will be retrieved and processed using DAKO PD-L1 immunohistochemistry 22C3 pharmDx Kit. PD-L1 stained slides will be reviewed by two pathologists independently, using the recommended scoring system. For cases where there is discrepancy, the two histopathologists will review the stains jointly and the consensus score will be used for data analysis.The tumour proportion score (TPS) will be documented for each sample according to the following categories:PD-L1 negative: <1%? 1-49%? 50%

Data management

Data sources

Data sources (types)
Disease registry
Other

Data sources (types), other
Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
No