EOLE - A cohort study of patients with advanced, unresectable (stage IIIB) metastatic (stage IV) non-squamous non-small cell lung cancer (NSCLC) or in relapse starting treatment with Avastin® in combination with chemotherapy as first line treatment of metastatic disease

Head :Medical data center

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General

Identification

Detailed name	A cohort study of patients with advanced, unresectable (stage IIIB) metastatic (stage IV) non-squamous non-small cell lung cancer (NSCLC) or in relapse starting treatment with Avastin® in combination with chemotherapy as first line treatment of metastatic disease
Sign or acronym	EOLE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22991

General Aspects

Medical area	Cancer research
Study in connection with Covid-19	No
Pathology (details)	Non-squamous non-small cell lung cancer
Health determinants	Medicine
Keywords	Bevacizumab

Scientific investigator(s) (Contact)

Name of the director	Medical data center
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No

Funding

Funding status	Private

Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No

Database objective

Main objective	This observational study will evaluate modality, efficacy and safety of Avastin (bevacizumab) as first-line treatment in combination with chemotherapy in patients with inoperable advanced, metastatic or recurrent non-squamous non-small cell lung cancer in clinical practice 1. To describe characteristics of patients treated with Avastin®: demographic and clinical characteristics, history of the disease, and previous disorders and conditions, 2. To describe methods of use of Avastin® in follow-up: doses and durations of treatment with Avastin® (number of cycles); chemotherapy treatments used in combination with treatment with Avastin®; discontinuation of treatment with Avastin® (temporary and permanent) and reasons;

	treatment strategies set up after discontinuation of treatment with Avastin®, 3. To describe overall survival of patients treated with Avastin®, 4. To describe the safety profile of treatment with Avastin®: serious and non-serious adverse events and targeted adverse events, 5. To describe quality of life: Spitzer's quality of life questionnaire, 6. To describe therapeutic management of patients with non-squamous cell NSCLC in first-line chemotherapy of metastatic disease not receiving Avastin®: compilation of an anonymous registry over a 3-month period starting with time of scientific set up by the investigator.
Inclusion criteria	Prospective cohort : - Adult, man or woman patient (age >= 18 years), - With unresectable locally advanced (stage IIIB), metastatic (stage IV) or recurrent non squamous (whenever the histology is not predominantly of squamous cell type) non-small cell lung cancer (NSCLC), and treated in first line setting - Patient starting for the first time a treatment with bevacizumab in first line setting, - Patient having received oral and written information on the study and having no objection to the fact that his (her) personal data will be subjected to data processing. Registry : - Patients with unresectable locally advanced (stage IIIB), metastatic (stage IV) or recurrent non squamous non-small cell lung cancer (NSCLC), and treated in first line setting, - Patients for whom the multidisciplinary committee decided to not initiate a treatment with bevacizumab, - Inclusion in the registry had to be consecutive during the first three months of study participation for each investigator.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except

	of lymphoid, haematopoietic and related tissue
Gender	Male Woman
Geography area	National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2011
Date of last collection (YYYY or MM/YYYY)	2013

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	418

Data

Database activity	Data collection completed
Type of data collected	Clinical data
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Followed pathology	C00-C75 - Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue
Links to administrative sources	No

Promotion and access

Promotion Access	
Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only