

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

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|---|-----------|
| Sponsor(s) or organisation(s) responsible | Roche SAS |
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|---------------------|---------|
| Organisation status | Private |
|---------------------|---------|

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|---|-----|
| Presence of scientific or steering committees | Yes |
|---|-----|

Additional contact

Main features

Type of database

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|------------------|-----------------|
| Type of database | Study databases |
|------------------|-----------------|

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|---------------------------|--------------|
| Study databases (details) | Cohort study |
|---------------------------|--------------|

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| Database recruitment is carried out by an intermediary | A selection of health institutions and services |
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| Database recruitment is carried out as part of an interventional study | No |
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Database objective

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|----------------|--|
| Main objective | <p>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</p> <ol style="list-style-type: none">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 \geq 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

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