

PEPITA - A prospective cohort study assessing the efficacy and safety of Tarceva® in 2nd line in patients with locally advanced or metastatic squamous Non-Small Cell Lung Cancer (NSCLC) - PEPiTA study

Head :Roche Medical Data Center

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General

Identification

Detailed name A prospective cohort study assessing the efficacy and safety of Tarceva® in 2nd line in patients with locally advanced or metastatic squamous Non-Small Cell Lung Cancer (NSCLC) - PEPiTA study

Sign or acronym PEPITA

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation

ML28195

General Aspects

Medical area Cancer research

Study in connection with Covid-19 No

Pathology (details) Non-Small Cell Lung Cancer (NSCLC)

Health determinants Iatrogenic
Medicine

Keywords ERLOTINIB

Scientific investigator(s) (Contact)

Name of the director Roche Medical Data Center

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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

Name of the contact <https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html>

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 made on the basis of: Medication(s) taken

Database recruitment is carried out as part of an interventional study No

Database objective

Main objective Primary objective: To describe Progression Free Survival (PFS) in patients with stage IIIB or IV squamous NSCLC initiating treatment with Tarceva® after failure of first-line platinum-based chemotherapy.

Secondary objectives:

- To describe characteristics of patients treated with Tarceva®;
- To describe Tarceva® treatment modalities in patients with squamous NSCLC after failure of first-line platinum-based chemotherapy;
- To evaluate Overall Survival (OS);
- To describe the evolution of QoL;
- To describe the safety profile of Tarceva®.

Inclusion criteria

Inclusion criteria:

1. Adult patients (age \geq 18 years);
2. Histologically and/or cytologically confirmed advanced (stage IIIB) or metastatic (stage IV) NSCLC with predominant squamous component (basaloid carcinomas allowed), after failure of first-line platinum-based chemotherapy;
3. For whom the treating physician decided to initiate treatment with Tarceva®;
4. Having received oral and written information about the study and having raised no objections to the collection and analysis of his/her personal data.

Exclusion criteria:

1. Mixed non-small cell and small cell lung carcinoma or mixed squamous cell carcinoma with a predominant adenocarcinoma component;
2. Concomitant participation in a clinical trial evaluating an antineoplastic treatment.

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

D02 - Carcinoma in situ of middle ear and respiratory system

Gender

Male
 Woman

Geography area

National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2012

| | |
|--|---|
| Date of last collection (YYYY or MM/YYYY) | 2014 |
| Size of the database | |
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | 152 |
| Data | |
| Database activity | Data collection completed |
| Type of data collected | Clinical data Biological data |
| Clinical data (detail) | Medical registration |
| Details of collected clinical data | Date of visit - Inclusion/exclusion criteria - Demographic data - ECOG - SAP/DAP - Social and occupational data - Risk factors (tobacco use) - Medical history and concomitant diseases - Treatment associated with initiation of Tarceva® - Disease history: primary lung tumor evaluation - Disease history: diagnosis of locally advanced or metastatic disease - EGFR mutation status - First-line treatment of metastatic NSCLC. |
| Presence of a biobank | No |
| Health parameters studied | Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception |
| Care consumption (detail) | Medicines consumption |
| Procedures | |
| Data collection method | eCRF |
| Classifications used | CDISC |
| Quality procedure(s) used | GCP/GVP |
| Participant monitoring | Yes |
| Monitoring procedures | Monitoring by contact with the referring doctor |
| 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 |
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| Presence of document that lists variables and coding procedures | Yes |
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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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