

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

Address 4 cours de l'Île Seguin - 92650 BOULOGNE-BILLANCOURT

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

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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