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 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 >= 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/eclusion 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
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only