TERRA - Study of a patient cohort with locally advanced or metastatic non-small cell lung cancer treated with Tarceva® (Erlotinib) monotherapy and without progression after at least nine months

Head :Roche Medical Data Center

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General

Identification

Detailed name	Study of a patient cohort with locally advanced or metastatic non-small cell lung cancer treated with Tarceva® (Erlotinib) monotherapy and without progression after at least nine months
Sign or acronym	TERRA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22973

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'Ile 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 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 the progression-free survival of a population of patients with metastatic or locally advanced NSCLC treated with Tarceva® monotherapy whose disease has not progressed for at least nine months. Secondary objectives:

	- To describe patients' characteristics at inclusion in the study and on initiation of treatment with Tarceva® monotherapy (demographic, clinical, and biological characteristics); - To describe the use of Tarceva®; - To evaluate the efficacy of treatment with Tarceva®: the best response obtained (complete response, partial response, or stabilisation), overall survival, and prognostic criteria for long-term survival on Tarceva®; - To describe the long-term safety profile of Tarceva®; - To describe the correlations between tumour biology and response to Tarceva®; - To describe patient adherence to Tarceva® monotherapy using the Morisky scale; - To describe the change in quality of life for patients treated with Tarceva® monotherapy, using the FACT-L questionnaire.
Inclusion criteria	Inclusion criteria: - Adult patients (age >= 18 years); - Treated with Tarceva® monotherapy for a locally advanced or metastatic NSCLC (stage IIIB/IV) and without disease progression for at least nine months; - Agreed to be monitored for the whole duration of the observation (24 months maximum); - Who received both oral and written information about the study without objection to their data being subject to automated processing. Exclusion criteria: - None.
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)	2010
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	217
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Validation of selection criteria - Information about the study - Demographic and general data - NSCLC history - Biomarkers if available - Performance status (ECOG) - Tarceva® therapy - Combined treatments - Anticancer treatments after Tarceva® permanent discontinuation - Disease progression - Adverse events under Tarceva® therapy, over the retrospective study period - Adverse events over the prospective study period - Reason for early study withdrawal.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
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