First-line anticancer drugs in patients with advanced, primary Non-Small Cell Lung Cancer: drug-utilization and effectiveness studies from Tuscany Region healthcare database

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/36693

EU PAS number

EUPAS36692

Study ID

36693

DARWIN EU® study

No

Study countries

Italy

Study description

The aim of the project is evaluate drug utilization and the effectiveness of first-line anticancer therapies approved for the treatment of advanced, non-resectable, NSCLC patients between 2009 and 2019 in the Tuscany population. Two studies will be thus performed on a cohort of patients with not-resectable, primary NSCLC: a drugs utilization study and a survival study. For the purpose of this study two different, already pseudo-anonymized, data sources will be used: pathology registry and administrative healthcare data of the Tuscany region.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

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Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **Not-for-profit** | **ENCePP partner**

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Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/08/2020

Actual: 08/08/2020

Study start date

Planned: 15/08/2020

Actual: 08/08/2020

Date of final study report

Planned: 15/12/2020

Actual: 08/08/2020

Sources of funding

- Other

More details on funding

No external funding

Study protocol

200808_Encepp_First-line_NSCLC.pdf(2.18 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The aim of the project is evaluate drug utilization and the effectiveness of first-line anticancer therapies approved for the treatment of advanced, non-resectable, NSCLC patients between 2009 and 2019 in the Tuscany population.

Study Design

Non-interventional study design

Cohort

Population studied

Short description of the study population

All patients with a NSCLC record in PR registry of Tuscany Region between January 1, 2009 and June 30, 2019 will be identified. Patients with a diagnosis of NSCLC will be selected using a specific algorithm for the PR.
The date of the first NSCLC diagnosis recorded in PR will be considered as the index date. Thereafter, the PR will be linked to regional AHD, in order to select patients with ≥18 years old and with at least two years of look back. In order to select only patients with a primary NSCLC, only patients without a cancer diagnosis other than lung cancer recorded in HDR in the 5 years before index date will be included in the study cohort.
Moreover, in order to avoid patients with a cancer recurrence, only patients with a lung cancer diagnosis (162* ICD-9CM) recorded between 3 months and 5 years before index date will be excluded.
In order to select only lung cancer patients with an advanced stage of the disease, patients without a lung surgery (ICD9-CM codes: 32*) in the six months before or after index date will be included.
we aim to exclude those patients receiving neoadjuvant therapy (generally less than six months), and those patients receiving adjuvant therapy (generally no more than six months after PR record).

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Non-small cell lung cancer patients

Estimated number of subjects

4500

Study design details

Outcomes

Drug utilization and survival

Data analysis plan

Descriptive analyses will be conducted to assess demographic and clinical characteristics of selected NSCLC patients in relation to the histology of NSCLC. Characteristics of patients according to first-line therapy registered will be compared using chi-square tests or Fisher exact test for categorical variables and ANOVA tests for continuous variables. In order to evaluate if squamous and non-squamous patients have a different profile on the basis of first-line treatment, a logistic regression model will be used (odds ratio and CI95%). Trend, seasonality and cyclical irregularity about the percentage of not treated patients and chemotherapy patients will be evaluated using a time series model. As for survival analysis, a COX proportional hazards model will be used to analyze predictors of survival. Results of the Cox model will be reported as HR with 95%CI. Finally, Kaplan Maier method will be used to describe OS.

Data management

Data sources

Data source(s)

ARS Toscana

Data source(s), other

ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Pathology registry

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No