DISPARITIES IN LUNG CANCER MANAGEMENT IN ITALY: A PUBLIC HEALTH STUDY

First published: 29/09/2021

Last updated: 14/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS43315

Study ID

43951

DARWIN EU® study

No

Study countries

☐ Italy

Study description

A Real-World Evidence, retrospective, longitudinal, cohort study based on data extracted from the Lazio (Italy) Regional Administrative databases. Study objective will be to investigate potential associations between socioeconomic factors and lung cancer outcomes such as survival rate, late diagnosis, or access to innovative cancer drugs

Study status

Ongoing

Research institutions and networks

Institutions

Department of Epidemiology of the Regional Health Service - Lazio

Italy

First published: 23/03/2010

Last updated: 22/06/2018

Institution | Outdated | EU Institution/Body/Agency | ENCePP partner

Contact details

Study institution contact

Valeria Belleudi v.belleudi@deplazio.it

Study contact

v.belleudi@deplazio.it

Primary lead investigator

Valeria Belleudi

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 22/09/2020

Study start date

Planned: 01/10/2021

Actual: 01/10/2021

Data analysis start date

Planned: 01/11/2021

Actual: 01/11/2021

Date of final study report

Planned: 01/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IQVIA Solutions SPA

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

Oss-R-244,Prot. 1072/CE Lazio 1

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

To investigate potential associations between socioeconomic factors and lung cancer outcomes such as survival rate, late diagnosis, or access to innovative cancer drugs

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Non-small cell lung cancer

Large cell lung cancer recurrent

Adenosquamous cell lung cancer

Population studied

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)

Estimated number of subjects

1000

Study design details

Outcomes

1. To measure the survival at 24 months for metastatic lung cancer patients 2. To measure the survival at 24 months for non-metastatic lung cancer patients,

• To estimate the probability to have metastasis since the first diagnosis • To estimate the probability of have a late lung cancer diagnosis • To calculate the use of innovative and expensive treatments

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Data analysis plan

All analyses will be performed using SAS® software version 9.4 or later. A Statistical Analysis Plan (SAP) will be prepared with description of all statistical methods performed. Qualitative variables will be reported using frequencies (n) and percentages (%), while quantitative variables through mean and standard deviation (SD), median and IQR. All variables will be included into the multivariate models. To estimate the survival in lung cancer patients, a multivariate, semi-parametric mixed model regression (Cox models) will be implemented. Results will be expressed as hazard ratio (HR) and the corresponding 95% confidence interval (95% CI). The risk of metastatic lung cancer diagnosis at first diagnosis and the probability to have access to innovative cure will be measured using unconditional mixed logistic models. The risk of metastatic lung cancer diagnosis will be measured at index date while access to innovative cure will be measured throughout the follow-up period

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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