Long-term non-interventional monitoring of patients newly diagnosed with bronchogenic carcinoma (LUCAS)

First published: 15/10/2018

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Study Ongoing

Administrative details

EU PAS number

EUPAS25626

Study ID

43265

DARWIN EU® study

No

Study countries

Czechia

Study description

Long-term non-interventional monitoring of newly diagnosed patients with bronchogenic carcinoma and their follow-up of up to 5 years. Epidemiology, diagnosis and treatment patterns will be monitored and evaluated.

Study status

Ongoing

Research institutions and networks

Institutions

Czech Medical Association of J. E. Purkyně

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Institution

Faculty hospital Olomouc Olomouc, Faculty hospital Hradec Kralove Hradec Kralove, Faculty hospital Motol Praha Praha, Faculty hospital Brno Brno, Faculty hospital Plzen Plzen, Faculty hospital Bulovka Praha

Contact details

Study institution contact

Martina Koziar Vasakova martina.koziarvasakova@ftn.cz

Study contact

martina.koziarvasakova@ftn.cz

Primary lead investigator

Martina Koziar Vasakova

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/05/2018

Actual: 12/09/2018

Study start date

Planned: 01/06/2018

Actual: 01/06/2018

Data analysis start date

Planned: 01/01/2019

Date of interim report, if expected

Planned: 31/12/2024

Date of final study report

Planned: 28/02/2025

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Roche, Takeda, MSD, Boehringer Ingelheim, Pfizer, BMS, Astra Zeneca, Sotio, Novartis, Celgene, UJV, Pneumoftizeology society of the Czech Medical Association of J. E. Purkyně

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 type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Disease registry - Assessment of scope and structure of care, treatment management, treatment sequencing, overall survival a progression-free survival

Main study objective:

Mapping the bronchogenic carcinoma patient journey through diagnosis and treatment. Continuous data analysis. Assessment of scope and structure of care, treatment management, treatment sequencing, survival analysis.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Disease Registry

Study drug and medical condition

Medical condition to be studied

Non-small cell lung cancer

Small 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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Estimated number of subjects

1.300

Study design details

Outcomes

Description of bronchogenic carcinoma population characteristics, diagnostic and treatment patterns in participating centers, evaluation of gaps vs guidelines. survival analysis

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Data analysis plan

In patients with lung cancer the goal is to estimate and to describe treatment regimens, patient pathway, sequencing of treatments, progression-free survival (PFS) and overall survival (OS). The analysis will use of descriptive statistical methods. Exploratory statistical testing and modelling will be used to highlight interesting aspects of the data. Any test performed will be two-sided and carried out with a 5% α error rate without correction for multiplicity. Analysis of

PFS and OS is based on the survivor function. All time-to-event analyses will be performed by using Kaplan-Meier methods including calculation of median survival times and 95% confidence intervals (CIs). Predictors and variables will be assessed. The study sponsor will also be able to perform ad hoc queries using the cohort data throughout the duration of the study 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)

Disease 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