Patient characteristics and treatment of non-small cell lung cancer (NSCLC) patients – a Danish nationwide registry study (20200328)

First published: 26/04/2021

Last updated: 15/12/2022

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50172

EU PAS number

EUPAS40607

Study ID

50172

DARWIN EU® study

No

Study countries

Denmark

Study description

Retrospective cohort study of locally advanced or metastatic non-small cell lung cancer (NSCLC) patients in a Danish nationwide cohort. The study will assess patient characteristics and treatment of patients with NSCLC. The source population is record-linkage data between the Danish Lung Cancer Register (DLCR), the Danish National Patient Registers (DNPR), the Danish Pathology Register (DPR), the Danish Civil Registration System, the Danish Prescription Registry, the National Laboratory Database Register, the National Health Insurance Service Register, the Danish education registers and the Income Statistics Register. Patients aged 18 and over at the time of NSCLC diagnosis, who were diagnosed with incident locally advanced or metastatic NSCLC between 1 Jan 18 - 30 Jun 20 will be included. Data on patients will be collected starting from date of locally advanced or metastatic NSCLC diagnosis until date of emigration, death or end of the study period (31 Dec 20), whichever occurs first.

Study status

Finalised

Research institutions and networks

Institutions

Copenhagen Phase IV Unit (Phase4CPH), Center for Clinical Research and Prevention

Denmark

First published: 16/11/2022

Last updated: 15/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility | ENCePP partner

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 06/11/2020

Study start date

Planned: 31/08/2021

Actual: 09/07/2021

Data analysis start date

Planned: 31/08/2021

Actual: 09/07/2021

Date of final study report
Planned: 09/06/2022

Actual: 16/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

01.02.06 Public Redacted Protocol Ver 1.0 English (3).pdf(1.96 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:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to estimate overall survival (OS) of patients with locally advanced or metastatic NSCLC

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective study

Study drug and medical condition

Medical condition to be studied

Non-small cell lung cancer

Population studied

Short description of the study population

Adults aged 18 years or older diagnosed with non-small cell cancer (NSCLC) identified from the Danish registries between 1 January 2018 to 30 June 2020.
Inclusion criteria:
- Adults aged ≥18 years at time of NSCLC diagnosis
- Diagnosed with incident locally advanced (Stage IIIB/C) or metastatic (Stage IV) NSCLC between 1 January 2018 to 30 June 2020.
Exclusion criteria:
- Patients who immigrated to Denmark less than one year before NSCLC diagnosis
- Patients initially diagnosed with Stage I-IIIa NSCLC and progressed to advanced NSCLC during the study period will be excluded

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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 cancer patients

Estimated number of subjects

8000

Study design details

Outcomes

Overall survival (OS), • Proportion of patients with locally advanced or metastatic NSCLC who are tested for KRAS • KRAS G12C mutation status • Demographics, clinical characteristics, tumor characteristics, treatment history (eg, line of therapy (LOT), type of treatment and time-to-next treatment (TTNT) and genetic mutation profile.

Data analysis plan

There are no formal hypotheses for the study. Descriptive analyses will be performed. To describe time-to-event (OS and TTNT), Kaplan-Meier (KM) curves will be plotted, and KM estimates will be calculated. For survival objectives, analyses will be performed by line of treatment (LOT) and type of therapy.

Documents

Study results

20200328_ORSR Abstract_06DEC2022_Redacted.pdf(687.17 KB)

Data management

Data sources

Data source(s), other

Danish Registries (access/analysis)

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