A Multicentre, Cohort Study to Assess the Impact on SYMptom Burden and Patient Health-related Quality of Life of Afatinib Treatment in Advanced Non-small Cell Lung Cancer in a Real World Setting in Greece (SYM-Less)

First published: 13/04/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS12887

Study ID

46770

DARWIN EU® study

No

Study countries

Greece

Study description

This non-interventional study will include a representative sample of patients with locally advanced or metastatic NSCLC harboring Epidermal Growth Factor Receptor (EGFR)-mutations in Greece. Eligible NSCLC patients, for whom the physician has decided to initiate treatment with the study medication (afatinib, GIOTRIF®) will be treated according to the local prescribing information and standard medical practice in terms of visit frequency and types of assessments performed. The study will investigate the impact of GIOTRIF (Afatinib) on patients' disease-related symptom burden and Health-Related Quality of Life (HRQoL) in a real world clinical setting in Greece.The Average Symptom Burden Index (ASBI) score of the Lung Cancer Symptom Scale (LCSS) in eligible patients, after 6 months of therapy, will be analyzed. The overall study duration period is expected to be 48 months, including a 36-month enrollment period and a minimum 12-month follow-up period.

Study status

Finalised

Research institutions and networks

Institutions

Boehringer Ingelheim

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Institution

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

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Primary lead investigator

MARIA KARMIRANTZOU

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 13/01/2016

Actual: 13/01/2016

Study start date

Planned: 16/02/2016

Actual: 16/02/2016

Data analysis start date

Planned: 01/03/2016

Actual: 01/03/2016

Date of final study report

Planned: 28/02/2022

Actual: 04/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer Ingelheim Hellas Single Member S.A.

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

Data collection methods:

Primary data collection

Main study objective:

To evaluate the impact of afatinib therapy on the patient-reported lung cancer-specific symptom burden over 6 months of therapy

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

GIOTRIF

Medical condition to be studied

Non-small cell lung cancer metastatic

Additional medical condition(s)

1) any histological type and 2) activating EGFR-mutations

Population studied

Short description of the study population

Patients with locally advanced or metastatic NSCLC harboring Epidermal Growth Factor Receptor (EGFR)-mutations in Greece. Eligible NSCLC patients, for whom the physician has decided to initiate treatment with the study medication (afatinib, GIOTRIF®) will be treated according to the local prescribing information and standard medical practice in terms of visit frequency and types of assessments performed.

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

128

Study design details

Outcomes

6-month symptom improvement rate using the LCSS ASBI questionnaire, 1.LCSS total & domain scores change from enrolment 2.ASBI score change from enrolment 3.Proportion of patients in the EQ-5D dimension levels change from enrolment 4.EQ-VAS score change from enrolment 5.ECOG PS score change from baseline 6.Ratio of afatinib doses actually taken 7.Discrepancy reasons between afatinib doses 8.Treatment discontinuation % of pts 9.Treatment interruption % of pts

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Data analysis plan

The study is not aimed to confirm/reject any pre-defined hypotheses,statistical analyses will be of explorative & descriptive nature.Continuous variables will be summarized with the use of descriptive statistical measures (mean, SD, median & extreme values) & categorical/distinct variables will be displayed as frequency tables.The normality of distribution of continuous variables will be examined using the Shapiro-Wilk test in order to determinewhether or not to use parametric methods for the analysis of the sample data.Differences between the mean values of continuous variables will be evaluated using the paired t-test or the non-parametric analogue (i.e.Wilcoxon signed rank test).All statistical tests will be two-sided & will be performed at a 0.05 significance level.The exact p-values will be reported, even for non-significant results, rounded to 3 decimals unless the p-alue is less than 0.001 (P<0.001 will be reported).No adjustment for multiplicity of testing will be performed.

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)

Other

Data sources (types), other

Prospective patient-based data collection

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