

Evaluation of the impact of a nurse-led telephone follow-up on treatment compliance of patients treated from a locally advanced or metastatic non-small-cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutation(s).The PARTAGE study.

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Study

Ongoing

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/12955>

EU PAS number

EUPAS12954

Study ID

12955

DARWIN EU® study

No

Study countries

France

Study description

Evaluation of the impact of nurse-led telephone on treatment compliance

Study status

Ongoing

Research institutions and networks

Institutions

[Hôpital Européen Georges Pompidou](#)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Florian SCOTTE

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/12/2015

Actual: 18/12/2015

Study start date

Planned: 15/10/2015

Actual: 18/12/2015

Data analysis start date

Planned: 18/06/2018

Date of final study report

Planned: 18/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Boehringer

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To evaluate, during routine clinical practice, the impact of nurse-led telephone follow-up on overall patient treatment compliance with oral targeted therapy (cumulated dose* during the 3-month follow-up).

Study drug and medical condition

Name of medicine

GIOTRIF

Medical condition to be studied

EGFR gene mutation

Lung cancer metastatic

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

500

Study design details

Outcomes

The impact of nurse-led telephone follow-up on overall patient treatment compliance, Patient and health care professional 's satisfactory, quality of life

Data analysis plan

At the inclusion visit (D0), the investigator will ask the patient whether he would like to participate in the study and will obtain his written consent. Patients agreeing to participate will be randomised (3:1 ratio) and included in one of the following 2 groups: Group without `remote additional personalised nurse-led follow-up: patients will receive the healthcare given routinely by their medical team (100 patients). Group with `remote additional personalised nurse-led follow-up: patients will receive telephone calls from a nurse in addition to the healthcare given routinely by their medical team (300 patients). All the patients will be seen according to normal practice by the study medical team. Patients in the group with `remote additional personalised nurse-led follow-up will be contacted 8 times during the s

Data management

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