Incidence and Resolution of Eribulin-induced peripheral Neuropathy (IRENE)

First published: 18/07/2016

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS14118

Study ID

50054

DARWIN EU® study

No

Study countries

☐ Germany

Study description

To characterize and determine the incidence of eribulin-induced peripheral neuropathy (PN), and frequency and time to resolution of eribulin-induced PN in patients treated with eribulin in a real life setting for locally advanced or

metastatic breast cancer (MBC), following one or two prior chemotherapeutic regimens for advanced disease.

Study status

Finalised

Research institutions and networks

Institutions

Eisai

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 60 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Yvonne Lamb

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/05/2016

Actual: 05/05/2016

Study start date

Planned: 08/08/2016

Actual: 12/08/2016

Date of interim report, if expected

Planned: 02/12/2019

Actual: 15/11/2019

Date of final study report

Planned: 31/12/2023

Actual: 18/04/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai

Study protocol

Halaven_Beobachtungsplan_PASS_1.0_ 06 May 2016 clean_FINAL_160602_signed.pdf (9.71 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

E7389-M044-504

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To characterize and determine the incidence of eribulin-induced PN, and frequency and time to resolution of eribulin-induced PN in patients treated with eribulin in a real life setting for locally advanced or MBC following one or two prior chemotherapeutic regimens for advanced disease.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, post authorization, single-arm, prospective, multicenter study

Study drug and medical condition

Medicinal product name

Medical condition to be studied

Breast cancer metastatic

Population studied

Short description of the study population

Female patients aged ≥18 years with locally advanced or metastatic breast cancer (MBC) treated with erubulin in a real life setting in Germany.
Inclusion criteria:
1. Locally advanced or MBC eligible for treatment with eribulin according to Fachinformation
2. Maximum of two prior chemotherapeutic regimens for advanced disease.
3. Age ≥18 years at the time of informed consent.
4. Ability to understand and willingness to respond to questions related to their health.
5. Decision for the patient to start treatment with eribulin has been made prior to inclusion in this study.
6. Signed written informed consent.

Exclusion criteria:
1. Previous treatment with eribulin in any line of treatment.
2. Contraindication according to Fachinformation of eribulin.
3. Pregnancy or lactation.
4. Participation in an interventional clinical trial at the same time.

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

Metastatic breast cancer patients

Estimated number of subjects

400

Study design details

Data analysis plan

Epidemiological methods will be employed for data analyses. Descriptive analyses will be performed of all collected data. For quantative variables, descriptive statistics will include the number of patients (n), the number of patients will missing values (Nmiss), mean, standard deviation, median, 25%, 75% and 90% and 95% quantiles, minimum and maximum.

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