GARDENIA: A Multi-country Observational Serial Chart Review Study of KANJINTI use in Europe

First published: 09/07/2019

Last updated: 02/10/2022

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49134

EU PAS number

EUPAS30108

Study ID

49134

DARWIN EU® study

No

Study countries

☐ France

- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Poland
- [ ] Romania
- [ ] Spain

Study description

This study will describe patient characteristics and the utilization of KANJINTI in routine clinical practice

Study status

Finalised

Research institutions and networks

Institutions

Amgen

- [ ] United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 68 centres are involved in the study

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

Planned: 05/03/2019

Actual: 05/03/2019

Study start date

Planned: 09/12/2019

Actual: 28/10/2019

Data analysis start date

Planned: 13/10/2021

Actual: 10/12/2021

Date of final study report

Planned: 12/10/2022

Actual: 29/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20180020_01.02.06 Public Redacted Protocol Ver 1.0 2019-04-16 English.pdf
(1.15 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:

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 describe the characteristics of breast cancer patients receiving KANJINTI

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single-arm, observational, serial chart review

Study drug and medical condition

Name of medicine

KANJINTI

Anatomical Therapeutic Chemical (ATC) code

(L01XC03) trastuzumab

trastuzumab

Medical condition to be studied

HER2 positive breast cancer

Population studied

Short description of the study population

Adult patients aged 18 years or older with human epidermal growth factor receptor 2 positive (HER2+) breast cancer receiving KANJINTI as treatment to understand the treatment patterns.

Inclusion criteria:

• Patients who have HER2+ breast cancer in any stage of disease whether metastatic or early

• Patients receiving or having received KANJINTI treatment according to the judgment of the physician, after adoption of KANJINTI on the institution formulary, in routine clinical practice

• Patients are aged ≥ 18 years at KANJINTI initiation

Exclusion criteria:

• Currently participation or planning to participate in a concurrent interventional clinical trial involving therapeutic agent(s)

• Have other cancer type(s), concurrent to breast cancer

• Patients that have not provided an informed consent, where required per country-specific regulations

• Patients whose medical chart is not available for data extraction

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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

Breast Cancer patients

Estimated number of subjects

500

Study design details

Outcomes

• Describe characteristics of breast cancer patients receiving KANJINTI• Describe if the patient was trastuzumab treatment naïve or if the patient was switched. For patients who received Herceptin, which route was used for administration (IV or SC). • Gather therapies given with KANJINTI• Describe reasons for KANJINTI discontinuation and subsequent treatment plan

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Data analysis plan

The approach to the statistical analysis will be generally descriptive. No formal hypotheses will be tested.Categorical data will be summarized by the number and percentage of patients in each category. Two-sided 95% CIs calculated using Wilson’s method where appropriate will be presented. Continuous data

will be summarized by mean (and 95% CI where appropriate), SD, median, lower and upper quartiles, and minimum and maximum values. Time-to-event endpoints (time from KANJINTI initiation to the specific events) will be summarized using Kaplan-Meier methodology.Analyses will be presented by treatment setting (neo-adjuvant, adjuvant, and metastatic) and trastuzumab initiation status (naïve new starter, switcher)

Documents

Study results

20180020_ORSR.pdf(140.39 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Medical record review

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