# 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

**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.

medinfo@amgen.com

**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

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**Study start date**

Planned: 09/12/2019

Actual: 28/10/2019

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**Data analysis start date**

Planned: 13/10/2021

Actual: 10/12/2021

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**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

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**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

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**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)

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**Special population of interest**

Other

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**Special population of interest, other**

Breast Cancer patients

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**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

## 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**

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