AN OBSERVATIONAL STUDY OF CARDIAC EVENTS IN PATIENTS WITH HER2- POSITIVE METASTATIC BREAST CANCER WHO HAVE A LEFT VENTRICULAR EJECTION FRACTION (LVEF) BETWEEN 40%-49% PRIOR TO INITIATING TREATMENT WITH KADCYLA®

First published: 12/10/2017

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS20684

Study ID

32784

DARWIN EU® study

No

Study countries

United States

Study description

This is an observational study of cardiac events in patients with HER2-positive metastatic breast cancer who have a left ventricular ejection fraction (LVEF) between 40-49% prior to initiating treatment with Kadcyla. This is a secondary data use following a single retrospective cohort design. Flatiron Health Analytic Database processes data from multiple electronic health records (EHRs), including oncology specific EHRs (e.g., OncoEMR) and general EHRs (e.g., Epic, Cerner). This processing includes both structured data (i.e., data points that are organized in a predefined manner, such as drop-down fields that reside in the EHR to capture a patient's gender or date of birth) and unstructured data (i.e., information that is not organized in a pre-existing data model, such as free text from a physician's note or lab report).

Study status

Finalised

Contact details

Study institution contact

Thibaut Sanglier global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Thibaut Sanglier

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/01/2016

Actual: 31/01/2016

Study start date
Planned: 23/11/2017

Actual: 21/11/2017

Data analysis start date
Planned: 23/11/2017

Actual: 21/11/2017

Date of interim report, if expected
Planned: 31/05/2018

Date of final study report
Planned: 31/05/2019

Actual: 09/04/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

F. Hoffmann-La Roche Ltd.

Study protocol

Prot BO39807 Kadcyla _Redacted.pdf (1.21 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

BO39807

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

Data collection methods:

Secondary use of data

Main study objective:

To describe the risk of cardiac dysfunction in a population of patients with metastatic breast cancer and a low LVEF (40-<50%), within 60 days prior to initiating Kadcyla.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

TRASTUZUMAB EMTANSINE

Medical condition to be studied

Left ventricular dysfunction

Population studied

Short description of the study population

The source population is the overall population reported in the EHR and managed in at least one of the U.S. oncology clinics taking part in the Flatiron health network from 01 January 2011 onwards.
Patients were included if they fulfill each of the following inclusion criteria:
1. Diagnosis of breast cancer (ICD-9 174.x or ICD-10 C50.x) and pathology confirmed by medical chart review. At least two visits in the EHR database on or after 01 January 2011 (in order to exclude patients not actually followed in clinical practice).
2. Initiating Kadcyla® treatment after the date of metastatic breast cancer diagnosis (confirmed by medical charts review).
3. Evidence of LVEF < 50% within 60 days prior to initiation of Kadcyla®.

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

0

Study design details

Outcomes

- Left ventricular ejection fraction (LVEF) values by time - The incidence rate and the cumulative incidence of LVEF decrease greater than 10% points from baseline, Congestive heart failure (CHF) event rate, incidence rate and cumulative incidence of CHF event observed during cohort’s follow-up. Relevant subgroup at risk will be analyzed separately to estimate CHF incidence rate and respective cumulative incidence. Event rate, incidence rate and their respective cumulative incidence will also be estimated for each of the other cardiac events of interest.

Data analysis plan

Analyses will be performed two times including one interim analysis and one final analysis.Categorical variables will be summarized using absolute frequencies and percentages, and continuous variables will be summarized using descriptive statistics (i.e. mean, median, standard deviation and range), separately for the whole study population and by relevant subgroups (e.g. patients with and without CHF at baseline). All statistical analyses will be performed in-house using Statistical Analysis System (SAS) 9.X or R.

Documents

Study results

BO39807_Kadcyla_Final CSR_Redacted.pdf (146.06 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)

Electronic healthcare records (EHR)

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