An Observational Study of Cardiac Events in Patients With HER2 Positive Early Breast Cancer Treated With Herceptin® (OHERA)

First published: 10/06/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9914

Study ID

23949

DARWIN EU® study

No

Study countries

- Austria
- Belgium
- Germany
- Hungary

Italy
Poland
Spain
Sweden
United Kingdom

Study description

This observational, single-arm cohort safety study has been designed to observe the occurrence of cardiac events in participants with HER2-positive early breast cancer treated with trastuzumab (Herceptin®) in daily clinical practice. All participants will be treated and monitored according to the local clinical practice. No additional procedures or visits in comparison with the usual clinical practice are planned for the study. Data will be collected from medical records for up to 5 years or until death, loss to follow-up, or withdrawal of informed consent.

Study status

Finalised

Research institutions and networks

Institutions

F. Hoffmann-La Roche

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Institution

Multiple centres: 199 centres are involved in the study

Contact details

Study institution contact

Mona Shing global.clinical_trial_registry@roche.com

Study contact

global.clinical_trial_registry@roche.com

Primary lead investigator

Mona Shing

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/05/2006

Study start date

Actual: 31/08/2007

Data analysis start date

Actual: 30/09/2008

Date of final study report

Planned: 31/05/2017

Actual: 23/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Hoffmann-La Roche

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

BO20652

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective will be to observe, in the routine clinical practice setting, the incidence of symptomatic congestive heart failure (CHF, New York Heart Association NYHA class II to IV) and cardiac death of participants diagnosed with HER2-positive early breast cancer who receive Herceptin® as per the approved Summary of Product Characteristics (SmPC).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational post-authorization safety study (PASS)

Study drug and medical condition

Medicinal product name

HERCEPTIN

Medical condition to be studied

HER2 positive breast cancer

Population studied

Short description of the study population

Patients with HER2-positive early breast cancer treated with trastuzumab (Herceptin®) in daily clinical practice.

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

HER-2 positive breast cancer patients

Estimated number of subjects

3.800

Study design details

Outcomes

- Incidence of NYHA class II, III, and IV symptomatic CHF- Incidence of cardiac death, - Association between demographic characteristics and incidence of symptomatic CHF and cardiac death - Time to onset of symptomatic CHF and other significant cardiac conditions - Time to recovery of symptomatic CHF and other significant cardiac conditions - Incidence of asymptomatic left ventricular dysfunction

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Data analysis plan

This is an observational study designed to observe the incidence of symptomatic CHF and other significant cardiac events in participants treated with Herceptin for early breast cancer. There is no predefined hypothesis testing. All analyses will be regarded as exploratory and performed annually, available interim data will be reported.Analysis for Primary Objective: The incidence of CHF and of cardiac deaths will be summarized for all participants treated with Herceptin, with 95% Pearson Clopper confidence interval (CI) calculated for the individual rates. The onset of CHF in relation to Herceptin administration will be displayed.Analysis for Secondary Objective: If data permit, characteristics like age, history of disease, and other known risk factors will be evaluated for their prognostic influence on the occurrence of CHF and cardiac death. Time to onset of CHF will be described and estimated using Kaplan-Meier procedures. Duration and time to recovery will be also described.

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, Participant medical records

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