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

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Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/23949

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 institution 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
Study contact

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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 data collection

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

Name of medicine
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
3800

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

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

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