UK – A DISEASE REGISTRY STUDY TO PROSPECTIVELY OBSERVE TREATMENT PATTERNS AND OUTCOMES IN PATIENTS WITH HER2-POSITIVE UNRESECTABLE LOCALLY ADVANCED OR METASTATIC BREAST CANCER (ESTHER)

First published: 26/03/2018

Last updated: 05/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/26411

EU PAS number
EUPAS23334

Study ID
26411

DARWIN EU® study
No

Study countries
United Kingdom

Study description
This disease registry is a prospective, multicentre, non-interventional study designed to observe anti-cancer treatment regimens and clinical outcomes with these regimens in patients with human epidermal growth factor receptor 2 (HER2)-positive unresectable

LA/mBC. Patients can be enrolled in the study irrespective of the anti-cancer treatment they are prescribed. Once a patient is enrolled in the study, she/he will be followed until death, withdrawal of consent or study termination, whichever occurs first.

Study status
Finalised

Research institution and networks

Institutions

F. Hoffmann-La Roche
First published: 01/02/2024
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Institution

The study will be performed at approximately 28 sites.

Contact details

Study institution contact
Trial Information Support Line (TISL)
Study contact

global.clinical_trial_registry@roche.com
Primary lead investigator
Alistair Ring
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
13/11/2014
Actual:
13/11/2014

Study start date
Planned:
23/02/2015
Actual:
23/02/2015

Data analysis start date
Planned:
16/03/2023
Actual:
19/04/2023

Date of final study report
Planned:
31/12/2024
Actual:
15/02/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche Products Limited

Study protocol

ML29659_PROTOCOL_Redacted.pdf(1.27 MB)

ML29659 - Protocol v5_03-Mar-2022_Redacted.pdf(806.25 KB)

Regulatory

Was the study required by a regulatory body?
No

Is the study required by a Risk Management Plan (RMP)?
Not applicable

Other study registration identification numbers and links

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
Disease epidemiology
Drug utilisation
Effectiveness study (incl. comparative)
Safety study (incl. comparative)

Data collection methods:
Primary data collection

Main study objective:
In patients with unresectable locally advanced (LA) or metastatic breast cancer (mBC), to observe the different anti-cancer treatment regimens and their sequencing throughout the course of the disease and to describe clinical outcome for each anti-cancer treatment regimen measured as progression-free survival (PFS).

Study drug and medical condition

Name of medicine
Herceptin
Kadcyla
Perjeta

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

Anatomical Therapeutic Chemical (ATC) code
(L01XC03) trastuzumab
(L01XC13) pertuzumab
(L01XC14) trastuzumab emtansine

Medical condition to be studied
Breast cancer

Additional medical condition(s)
HER2-Positive Unresectable Locally Advanced or Metastatic Breast Cancer

Population studied

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)

Estimated number of subjects
300

Study design details

Setting
All eligible subjects were invited to participate in the study and enrolled sequentially. No other pre-selection criteria were applied.
Subjects met the following inclusion criteria for study entry:
- Males or females
- Initially diagnosed with HER2-positive unresectable LA/mBC no more than 6 months prior to enrolment, although they could have received anti-cancer treatment during that time
- Age ?18 years
- Able and willing to provide written informed consent and to comply with the study protocol
No exclusion criteria were applied.

Outcomes
In patients with unresectable LA/mBC, to observe the different anti-cancer treatment regimens and their sequencing throughout the course of the disease and to describe clinical outcome for each anti-cancer treatment regimen measured as progression-free survival (PFS). To observe safety profiles of different anti-cancer treatment regimens through reporting of serious adverse events (SAEs), specific adverse events relevant to HER2-targeted therapies and AEs leading to discontinuation or dose modification of an anti-cancer therapy, to describe incidence of and reasons for anti-cancer treatment modifications and treatment of populations of special interest.

Data analysis plan
All enrolled patients who received at least one dose of an anti-cancer medication for HER2-positive unresectable LA/mBC will be included in the full analysis set, which will be the primary analysis population for safety and efficacy parameters. Other analysis populations may be defined based on more restrictive criteria. The analysis of the present study will be exploratory and primarily make use of descriptive statistical methods. In addition, exploratory statistical testing and modelling will be used to highlight interesting aspects of the data. Any test performed will be two-sided and carried out with a 5% ? error rate without correction for multiplicity. A descriptive analysis of safety will be performed. The main safety parameter is the incidence of SAEs. The proportion of patients experiencing at least one event within each line of treatment will be estimated with 95% Clopper–Pearson CIs.

Documents

Study report
ML29659-Clinical_Study_Report_Synopsis_Redacted.pdf(532.61 KB)

Data management

Data sources

Data sources (types)
Disease registry
Electronic healthcare records (EHR)
Other

Data sources (types), other
Prospective patient-based data collection

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
Unknown