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: 02/07/2025

Study Finalised

Administrative details

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 institutions 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)
global.clinical_trial_registry@roche.com

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

ML29659, ESTHER

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

(L01FD01) trastuzumab

trastuzumab

(L01FD02) pertuzumab

pertuzumab

(L01FD03) trastuzumab emtansine

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% α 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)

Study publications

A disease registry study to prospectively observe treatment patterns and outcom…

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)

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