A PROSPECTIVE, NON-INTERVENTIONAL STUDY ASSESSING THE DIAGNOSTIC, THERAPEUTIC PROCEEDINGS AND SAFETY OF ANTI-HER2 TREATMENT IN ELDERLY PATIENTS (≥70 YEARS OLD) WITH HER2 POSITIVE BREAST CANCER IN ROUTINE CLINICAL PRACTICE IN POLAND - MULTICENTER, OBSERVATIONAL STUDY (HEROLD) (HerOld)

First published: 12/07/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS24812

Study ID

36953

DARWIN EU® study

No

Study countries

☐ Poland

Study description

This is a single cohort, observational, local, multicenter, prospective primary data collection, non-interventional Post Authorization Safety Study (NI-PASS). Data from Polish patients diagnosed with HER2-positive breast cancer that are being qualified and treated in NHF Drug Program “Treatment of the Breast Cancer” will be prospectively collected during three-year period (one year of recruitment and up to two years of observation). For patients that failed qualification to NHF Drug Program “Treatment of the Breast Cancer”, reasons for disqualification will be collected and no further observation in the study will take place.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 6 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Agnieszka Jagiełło-Gruszfeld

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/04/2018

Study start date

Planned: 31/07/2018

Actual: 17/09/2018

Date of final study report

Planned: 30/06/2022

Actual: 30/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Roche

Study protocol

ML40006_Protocol_Redacted.pdf.pdf (939.38 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

ML40006

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:

Primary Objectives - SafetyThe safety objectives of this study pertain to a subgroup consisting of patients ttreated with anti-HER2 treatment (Herceptin SC or Herceptin IV with or without Perjeta IV).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Post Authorization Safety Study

Study drug and medical condition

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

TRASTUZUMAB

PERTUZUMAB

Medical condition to be studied

HER2 positive breast cancer

Population studied

Short description of the study population

The following patients were enrolled into the study: all 70 years or older patients diagnosed with early, locally advanced or metastatic HER2 positive breast cancer who had agreed to participate in this study conducted in local research centers, regardless of the planned therapeutic proceedings.

The target population for this study will be:

• Elderly postmenopausal women (70 years old or above) diagnosed with HER2-positive breast cancer confirmed by validated immunohistochemistry (IHC) or in situ hybridization (ISH) methods

• The study will enroll patients who are eligible for anti-HER2 therapy as well as patients who were disqualified from anti-HER2 treatment

• Eligible patients scheduled for neoadjuvant, adjuvant or metastatic treatment with Herceptin subcutaneous or intravenous formulation with or without Perjeta IV in realworld settings, according to NHF drug program “Treatment of Breast Cancer” in Poland. Baseline visit and follow up will be planned according to local standards and NHF drug program “Treatment of Breast Cancer” requirements in Poland.

Patients must meet the following criteria for study entry:

• Elderly female postmenopausal patients: ≥70 years of age

• Postmenopausal - defined as at least 60 years of age, having undergone bilateral oophorectomy, medically confirmed ovarian failure or younger than 60 years of age and having had cessation of regular menses for at least 12 consecutive months with no alternative pathological or physiological cause and having serum levels of estradiol and follicle stimulating hormone within the laboratory's reference range for postmenopausal females
• Histologically or cytologically confirmed and documented adenocarcinoma of the breast (all breast cancer stages, all patients)
• HER2-positive (defined as either IHC3+ or in situ hybridization (ISH) positive) as assessed by local laboratory on primary tumor and/or metastatic site if primary tumor is not available (ISH positivity is defined as ratio of 2.0 or for the n

Age groups

- 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

150

Study design details

Outcomes

Safety objectives: Frequency of discontinuation of anti-HER2 treatment caused by adverse events (AEs), evaluate safety of anti-HER2 treatment and frequency of AEs, Serious AEs (SAEs), and AEs of special interest (AESIs),frequency of anti-HER2 treatment interruptions, discontinuation, reintroduction, and assess the completion of the assumed treatment plan. Effectiveness Objectives: epidemiological info for included patients, diagnostic proceedings before qualification, anticancer therapies before qualification/disqualification, info for the qualification process and reasons for disqualification, concurrent anticancer therapies, timing/type of surgery/radiotherapy in eBC patients who at start received neoadjuvant anti-HER2 therapy with Herceptin SC.

Data analysis plan

As no formal hypothesis will be tested in this non-interventional study, all analyses will be descriptive in nature. Descriptive statistics will include at least number of subjects, mean, standard deviation, minimum, and maximum for quantitative variables, and frequency and percentage for categorical variables. Additionally, 95% confidence interval will be provided. When relevant, statistical analyses for patients receiving anti-HER2 medication will be carried out by treatment arms of NHF Drug Program “Treatment of the Breast Cancer” as well as stage (early or locally advanced and metastatic breast cancer). Statistical analysis will be carried out by the treatment arm only for the descriptive analysis, no intent to statistically compare Herceptin IV to SC formulation.

Documents

Study results

ML40006_(HerOld)_CSR_Synopsis_Redacted.pdf (283.49 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)

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

No