Demographics and treatment patterns of Turkish female HR (+) HER2 (-) mBC patients in real life setting

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46630

EU PAS number

EUPAS43182

Study ID

46630

DARWIN EU® study

No

Study countries

☐ Türkiye

Study description

To describe patient demographics, clinical and disease characteristics and treatment patterns of Hormone-receptor positive HR (+) HER2 (-) locally advanced and metastatic breast cancer (mBC) women treated in the routine practice setting in Turkey.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

First published: 01/02/2024

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Institution

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact

Özge Fulya Öztürk

Study contact

ozgefulya.ozturk@pfizer.com

Primary lead investigator

Özge Fulya Öztürk

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 08/10/2021

Actual: 08/10/2021

Study start date

Planned: 20/10/2021

Actual: 25/10/2021

Date of final study report

Planned: 01/08/2022

Actual: 28/12/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer PFE İlaçları A.Ş.

Study protocol

A5481172_Study_Protocol_V1.pdf(1.91 MB)

A5481172_Study Protocol_V2.pdf(244.31 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe patient demographics, clinical and disease characteristics and treatment patterns of Hormone-receptor positive HR (+) HER2 (-) locally advanced and metastatic breast cancer (mBC) women treated in the routine practice setting in Turkey.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective, multicentered, observational study

Study drug and medical condition

Medical condition to be studied

Breast cancer metastatic

Additional medical condition(s)

Disease characteristics when starting treatment: breast cancer,stage (locally advanced, metastatic), appearance of advanced disease (de novo,,recurrent), metastases location (visceral, bone only),Comorbidities –Ischemic heart disease, heart failure, depression, cerebrovascular,disease, diabetes, osteoporosis, hypothyroidism and others

Population studied

Short description of the study population

The study population involved female patients with metastatic breast cancer aged 18 years or older identified between 01 January 2019 and 31 December 2020.

Inclusion criteria:

1. Being a Turkish citizen
2. Being older than 18 year-old women
3. Hormone positive (>1% hormone positive) and human epidermal growth factor receptor 2 negative patients
4. Patients that treated with specified dose in the below:

i) Patients with first-line (1L) mBC treatment whose treatment duration started in January 2019 - December 2020.

ii) Patients with second-line (2L) mBC treatment duration started in January 2019-December 2020.

iii) Patients with third-line (3L) mBC treatment duration started in January 2019-December 2020.

5. Patients with locally advanced or metastatic disease who are not suitable for curative treatment.

Exclusion criteria:

1. Patients meeting any of the following criteria will not be included in the study:

i) Patients without treatment information from previous lines (only for the second line and third line treated patients),

ii) HER2 positive patients' data will be excluded from the study.

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

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

Other

Special population of interest, other

Metastatic breast cancer patients

Estimated number of subjects

1000

Study design details

Outcomes

To determine rate of chemotherapy and endocrine therapy for HR (+) HER2 (-) metastatic breast cancer patients. To evaluate the responses to treatments (chemotherapy and endocrine therapy) used in routine clinical practice in patients with mBC in Turkey Demographics of treated all HR+ HER2- mBC patients To determine the treatment pattern: dose reduction rate To determine the disease characteristics when starting treatment: breast cancer stage (locally advanced, metastatic), appearance of advanced disease

Data analysis plan

Descriptive statistics will be used for continuous variables. Variables that met the normal distribution will be considered as mean and standard deviation, ordinal variables or variables that do not met the normal distribution will be evaluated as medians and ranges, categorical variables will be evaluated as numbers and percentages. Survival analysis will be performed using the Kaplan-Meier estimator for univariate analysis and the Log-rank test for in-group comparisons. For all comparisons, $p < 0.05$ will be considered for statistical significance. Statistical Package for Social Sciences (SPSS) 19.0 for Windows program will be used for data analysis.

Documents

Study results

A5481172 PAS-NIS Report Abstract.pdf(1.76 MB)

Study report

A5481172 Voluntary PAS-NIS Report.pdf(3.82 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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