

Safety evaluation of biosimilar trastuzumab in breast cancer: Experience of Colombian institutions

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Study

Planned

Administrative details

EU PAS number

EUPAS49290

Study ID

50108

DARWIN EU® study

No

Study countries

Colombia

Study description

The primary objective is to describe the frequency of adverse events by degree of severity and anatomical group to detail the safety profile of the biosimilar trastuzumab used for breast cancer in Colombian healthcare institutions. A descriptive, retrospective study will be performed on patients treated with biosimilar trastuzumab according to the approved indications for use in breast cancer at the Colombian institutional health service providers (IPS). Data for the study will be collected from the database and clinical records available in the IPS participating in the study, which are reference centers for the management of cancer patients in Colombia. The initial follow-up date will be in October 2019, after approval of sanitary registration. The patient's index date will be defined as the date of the first infusion of biosimilar trastuzumab. The follow-up time will end when the patient discontinues the treatment, dies, is lost to follow-up or until the end of the collection of information in July 2022. The database and the clinical records of the patients will be the only secondary sources of information. The clinical and treatment variables collected in the study will be recorded in CRF designed for the study. Main variables: Safety profile of biosimilar trastuzumab, Overall survival and progression-free survival, and Tumor response. There is no a priori hypothesis that indicates that sample size calculations can be applied

Study status

Planned

Research institutions and networks

Institutions

[Hospital San Ignacio](#)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ricardo Ballesteros

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/11/2022

Study start date

Planned: 05/12/2022

Date of final study report

Planned: 31/07/2023

Sources of funding

- Pharmaceutical company and other private sector
- Other

More details on funding

Pfizer S.A.S, Hospital San Ignacio

Study protocol

[A6181236_Protocolo Biosimilares_V1_07Oct2022_ENG.pdf](#) (1011.19 KB)

[A6181236_PROTOCOL V2.0_15Feb2023_ENG_Final.pdf](#) (1.29 MB)

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 type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Other

If 'other', further details on the scope of the study

Profile the safety of the biosimilar trastuzumab in Colombia

Main study objective:

To describe the frequency of adverse events by degree of severity and anatomical group to detail establish the safety profile of the biosimilar trastuzumab used for breast cancer in Colombian healthcare institutions.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective descriptive study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01FD01) trastuzumab

trastuzumab

Medical condition to be studied

Breast cancer metastatic

Additional medical condition(s)

Adjuvant 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

100

Study design details

Outcomes

Secondary Objectives: Perform the clinical characterization of patients who were treated with the biosimilar trastuzumab for breast cancer. Exploratory objectives: a) To calculate the overall survival (OS) and progression-free survival (PFS) in patients treated with the biosimilar trastuzumab for breast cancer, b) To explore the factors associated with effectiveness and safety in patients treat

Data analysis plan

Descriptive statistics will be produced for all variables. These will include estimates of the mean, standard deviation, 95% confidence intervals of the mean, median, interquartile ranges and frequency distributions for continuous scale variables and frequency distributions for categorical scale variables. The normality of the continuous variables will be assessed using the Kolmogorov test or the Shapiro Wilk test according to the number of samples collected. Time to event data including time to disease progression, death, partial response and complete response will be described using the Kaplan Meier estimator of the Survival Function. Associated factors of response to treatment will be identified among patient, disease and treatment parameters using Cox Proportional Hazard Models. The main factors that would be assessed in these analyses: Age, Diagnosis date, Stage, ECOG Status, Metastasis, Sites of metastasis, treatment received and AE. Log rank test will be used to compare the d

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)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Data for the study will be collected from the database and clinical records available in the IPS participating in the study

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