

HERMIONE - An Observational Study of the Safety of Herceptin Given Subcutaneously in Patients With Early HER2-positive Breast Cancer

Head :Roche Medical Data Center

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General

Identification

Detailed name	An Observational Study of the Safety of Herceptin Given Subcutaneously in Patients With Early HER2-positive Breast Cancer
Sign or acronym	HERMIONE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML28983

General Aspects

Medical area	Cancer research
Study in connection with Covid-19	No
Pathology (details)	Early HER2+ Breast cancer
Health determinants	Iatrogenic Medicine
Keywords	Herceptin® SC

Scientific investigator(s) (Contact)

Name of the director	Roche Medical Data Center
Address	4 cours de l'Île Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No
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Funding

Funding status	Private
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Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
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Organisation status	Private
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Presence of scientific or steering committees	Yes
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Additional contact

Name of the contact	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
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Main features

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is made on the basis of:	Medication(s) taken
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Database recruitment is carried out as part of an interventional study	No
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Database objective

Main objective	<p>Primary objective: To describe the systemic safety and local tolerability of subcutaneous Herceptin® (SC) in patients with HER2-positive early breast cancer (eBC), naive and non-naive of HER2+ treatment, treated in the neoadjuvant and adjuvant setting in routine clinical practice use.</p> <p>Secondary objective: To describe the quality of life (QoL) of patients (using the European Organization for Research and</p>
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Treatment of Cancer [EORTC] QLQ-C30 questionnaire)

- The description of the baseline and disease characteristics of patients with HER2+ eBC initiating a treatment with Herceptin® SC;
- The description of use of Herceptin® SC (treatment duration, frequency of injections and sites of injection).

Inclusion criteria

Inclusion criteria:

- Woman suffering from HER2+ early-stage Breast cancer (Stage I, stage IIA, stage IIB, or stage IIIA breast cancer);
- Woman eligible for neoadjuvant or adjuvant HER2+ treatment, according to national guidelines;
- Woman aged 18 years or older;
- Woman having received oral and written information about the study, without any objections for the use of her personal data and having signed a written informed consent form.

Exclusion criteria:

- Woman previously treated with Herceptin® subcutaneous;
- Woman participating in a clinical trial assessing an anticancer treatment.

Population type

Age

Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)
Great age (80 years and more)

Population covered

Sick population

Pathology

D05 - Carcinoma in situ of breast

Gender

Woman

Geography area

National

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)

2015

Date of last collection (YYYY or MM/YYYY)

2016

Size of the database

Size of the database (number of individuals) [500-1000] individuals

Details of the number of individuals 511

Data

Database activity Data collection completed

Type of data collected Clinical data
Biological data

Clinical data (detail) Medical registration

Details of collected clinical data Validation of inclusion and exclusion criteria - Dates of visits (or data of last contact with the patient) - Demographic - CKD history and evolution - Comorbidities - Most recent clinical and biological data - Previous and/or ongoing CKD treatments - Other specific treatments - Previous and/or ongoing anemia treatments - Treatment with Micera® - Adverses events - Reason for early study discontinuation.

Presence of a biobank No

Health parameters studied Health event/morbidity
Health event/mortality
Health care consumption and services
Quality of life/health perception

Care consumption (detail) Medicines consumption

Procedures

Data collection method eCRF

Classifications used CDISC

Quality procedure(s) used GCP/GVP

Participant monitoring Yes

Monitoring procedures Monitoring by contact with the referring doctor

Followed pathology D05 - Carcinoma in situ of breast

Links to administrative sources No

Promotion and access

Promotion

Access

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
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Presence of document that lists variables and coding procedures	Yes
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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