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'Ile Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No

Funding

Funding status	Private

Governance of the database

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

Additional contact

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

Main features

Type of database

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

Database objective

Main objective	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. Secondary objective: To describe the quality of life (QoL) of patients (using the European Organization for Research and

	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
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only