LORHA - A Retrospective Study to Characterize Patients With HER2-positive Metastatic or Locally Advanced Breast Cancer, Treated by Herceptin® as 1st Line-therapy and Without Progression for at Least 3 Years Followed by a 1-year Prospective Study for Patients Still Alive

Responsable(s) :Roche Medical Data Center

Date de modification : 23/08/2022 | Version : 1 | ID : 74136

Général

Identification

Nom détaillé	A Retrospective Study to Characterize Patients With HER2-positive Metastatic or Locally Advanced Breast Cancer, Treated by Herceptin® as 1st Line-therapy and Without Progression for at Least 3 Years Followed by a 1-year Prospective Study for Patients Still Alive
Sigle ou acronyme	LORHA
Numéro d'enregistrement (ID-RCB ou EUDRACT, CNIL, CPP, etc.)	ML23001

Thématiques générales

Domaine médical	Cancer research
Etude en lien avec la Covid-19	No
Pathologie, précisions	HER2-positive Metastatic or Locally Advanced Breast Cancer
Déterminants de santé	Iatrogenic Medicine
Mots-clés	Herceptin

Responsable(s) scientifique(s)

Nom du responsable	Roche Medical Data Center
Adresse	4 cours de l'Ile Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
Organisme	Roche SAS

Collaborations	
Participation à des projets, des réseaux, des consortiums	No
Financements	
Financements	Private
Gouvernance de la base de données	
Organisation(s) responsable(s) ou promoteur	Roche SAS
Statut de l'organisation	Secteur Privé
Existence de comités scientifique ou de pilotage	Yes
Contact(s) supplémentaire(s)	
Nom du contact	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Caractéristiques	
Type de base de données	
Type de base de données	Study databases
Base de données issues d'enquêtes, précisions	Cohort study
Origine du recrutement des participants	A selection of health institutions and services
Critère de sélection des participants	Medication(s) taken
Le recrutement dans la base de données s'effectue dans le cadre d'une étude interventionnelle	No
Objectif de la base de données	
Objectif principal	Primary objective: This observational study will characterize retrospectively patients with HER2-positive metastatic or locally advanced breast cancer who had received treatment with Herceptin

	(trastuzumab) in 1st line and who were without progression for at least three years. Secondary objectives: The secondary objectives of this study were to describe: - The progression-free survival, time to progression and patients overall survival; - Modalities of use of trastuzumab, the duration of treatment and the reasons leading to treatment discontinuation; - Antineoplastic treatments in combination with trastuzumab and after discontinuation of trastuzumab treatment; - Relevant biological tumor markers; - The safety of trastuzumab treatment.
Critères d'inclusion	Inclusion criteria: - Woman >= 18 years; - With HER2-positive metastatic breast cancer or locally-advanced breast cancer; - Treated with trastuzumab as first-line therapy; - Without progression for at least 3 years after initiation of trastuzumab treatment; - Alive or not alive, and treated or not treated with trastuzumab at the time of inclusion; For patients alive at the time of inclusion: - Having been informed orally and in writing about the study and having given their written consent to the automatic processing of her personal data and their consultation by a duly authorized third party; - For the patients who accepted the centralized histological analysis of their primitive tumor, a written consent. Exclusion criteria: - Disease progression <3 years after beginning 1st-line therapy with Herceptin.
Type de population	
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 concernée	Sick population
Pathologie	D05 - Carcinoma in situ of breast
Sexe	Woman

Champ géographique	National
Collecte	
Dates	
Année du premier recueil	2011
Année du dernier recueil	2012
Taille de la base de données	
Taille de la base de données (en nombre d'individus)	< 500 individuals
Détail du nombre d'individus	160
Données	
Activité de la base	Data collection completed
Type de données recueillies	Clinical data
Données cliniques, précisions	Medical registration
Détail des données cliniques recueillies	evaluation/inclusion criteria - initial breast cancer diagnosis - neo-adjuvant treatments - adjuvant treatments - entry in metastatic or locally advanced disease - adverse events since Herceptin® initiation - Progression - Evaluation at M6 and M12 - chemotherapy in 1st, 2nd and 3rd lines - hormonotherapy in 1st, 2nd and 3rd lines - Progression after 1 and 2nd lines - treatment by Herceptin® in neo-adjuvant/adjuvant - treatment by Herceptin® in metastatic
Existence d'une biothèque	No
Paramètres de santé étudiés	Health event/morbidity Health event/mortality Health care consumption and services
Consommation de soins, précisions	Medicines consumption
Modalités	
Mode de recueil des données	eCRF
Nomenclatures employées	CDISC
Procédures qualité utilisées	GCP/GVP

Suivi des participants	Yes
Modalités de suivi des participants	Monitoring by contact with the referring doctor
Appariement avec des sources administratives	No

Valorisation et accès

Valorisation et accès

Accès

Site internet dédié	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Existence d'un document qui répertorie les variables et les modalités de codage	Yes
Accès aux données agrégées	Access on specific project only
Accès aux données individuelles	Access on specific project only