

HERABLE - HER-2 Status in Gastric and Gastro-Oesophageal Junction Cancer

Head :Roche Medical Data Center

Last update : 08/23/2022 | Version : 1 | ID : 74137

General

Identification

Detailed name HER-2 Status in Gastric and Gastro-Oesophageal Junction Cancer

Sign or acronym HERABLE

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation ML27940

General Aspects

Medical area Cancer research

Study in connection with Covid-19 No

Pathology (details) Gastric and gastro-oesophageal junction cancer

Health determinants Medicine

Keywords HER2

Scientific investigator(s) (Contact)

Name of the director Roche Medical Data Center

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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 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: Positive HER2 status is defined as IHC3+ or IHC2+/ISH+, as per the Herceptin® SPC.

Secondary objectives:
Evaluated according to HER2 status determined by the centralized laboratory

- Describe pathological features of the tumors (assessed locally) according to HER2 status;
- Evaluate concordance between IHC 4B5 and SISH results for each sample;
- Evaluate concordance between HER2 status determined on biopsies and surgical specimens (globally and according to use or not of

neoadjuvant chemotherapy);
 - Describe expression of the following markers:
 HER3, HER4, PTEN, cMET, Bcl2, p53.

Inclusion criteria	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> - Gastric or GEJ adenocarcinoma specimens, regardless of stage, histologically documented (biopsy, surgical specimen, lymph node or distant metastasis); - Enough tumor material available to allow for the centralized analysis; - Specimens fixed and embedded in paraffin; - From a patient who was informed about the study orally and in writing by the oncologist or gastroenterologist, with a signed certificate of no objection. <p>Exclusion criteria:</p> <ul style="list-style-type: none"> - Fixatives not allowed: Bouin's solution.
Population type	
Age	<p>Adulthood (19 to 24 years)</p> <p>Adulthood (25 to 44 years)</p> <p>Adulthood (45 to 64 years)</p> <p>Elderly (65 to 79 years)</p> <p>Great age (80 years and more)</p>
Population covered	Sick population
Pathology	D00 - Carcinoma in situ of oral cavity, oesophagus and stomach
Gender	<p>Male</p> <p>Woman</p>
Geography area	National
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2012
Date of last collection (YYYY or MM/YYYY)	2014
Size of the database	
Size of the database (number of individuals)	< 500 individuals

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

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

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