METACOST - Observational Study on the management of HER2-positive breast cancer with brain metastases and its associated costs

Head :Leclerc-Zwirn Christel, Laboratoire GSK

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General

Identification

Detailed name	Observational Study on the management of HER2-positive breast cancer with brain metastases and its associated costs
Sign or acronym	METACOST
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 1410836

General Aspects

Medical area	Cancer research
Keywords	breast, oncology, metastasis, retrospective, cost

Scientific investigator(s) (Contact)

Name of the director	Leclerc-Zwirn
Surname	Christel
Phone	+33 (0)1 39 17 86 96
Email	christel.c.leclerc-zwirn@gsk.com
Unit	Laboratoire GSK

Collaborations

Funding

Funding status	Private
Details	GSK laboratory

Governance of the database

Sponsor(s) or organisation(s) responsible	Laboratoire GSK
Organisation status	Private

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Longitudinal study (except cohorts)
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Selection in each center (via PMSI and the DIM (medical information department) doctor of the investigating center) of a list of potentially eligible patients (patients who have had breast cancer with SNC metastases between 2006 and 2008). The presence or not of an overexpression of the HER2 status is then codes by the oncologist.

Database objective

Main objective	Describe the medical care of patients who have one or several secondary brain metastases to a primary breast cancer overexpressing HER2 and evaluate the cost of this from a health insurance standpoint
Inclusion criteria	? Patients from breast cancer with brain metastase(s) ? with overexpressing the HER2 receptor ? with brain metastases diagnosed between January 1, 2006 and December 31, 2008

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

Gender	Woman
Geography area	National
Detail of the geography area	France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2010
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	220

Data

Database activity	Data collection completed
Type of data collected	Clinical data Biological data Administrative data
Clinical data (detail)	Direct physical measures
Biological data (detail)	Histology of the tumor, mitotic index and presence of specific receptors (estrogens, progesterone, HER2)
Administrative data (detail)	PMSI (GHM, drugs)
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Filling out e-CRFs by a CRA of the CRU of the investigating center in collaboration with the oncologist.
Participant monitoring	Yes
Details on monitoring of participants	6 months, 12 months, 18 months and 24 months
Links to administrative sources	Yes
Linked administrative sources (detail)	PMSI
Promotion and access	
Promotion **Access**	
Terms of data access (charter for data provision, format of data, availability delay)	Publications
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only