LAPS - Female patients with breast cancer treated with lapatinib in the context of an expanded access program (ATU): description of the care trajectory and clinical course

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General

Identification

Detailed name	Female patients with breast cancer treated with lapatinib in the context of an expanded access program (ATU): description of the care trajectory and clinical course
Sign or acronym	LAPS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 1213267

General Aspects

Medical area	Cancer research
Others (details)	Breast cancer
Keywords	HER2+, Tyverb

Scientific investigator(s) (Contact)

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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)	Not-repeated cross-sectional studies (except case control studies)
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
Additional information regarding sample selection.	One hundred centers have filed at least one TUA request as of July 31, 2007 (about 3 months before the initiation of the study): about thirty of these are centers of substantial size (at least 5 patients, 10 patients on the average), the other 70 are small centers (less than 5 patients, 4 patients on the average). The study will be proposed to 80% of the centers in each stratum (center size). The random drawing will make it possible, as such, to retain 56 small centers and 25 large centers. Based on an estimated response rate of 70%, 40 small centers and 18 large centers will in the end participate in the study: Random drawing and number of patients expected: Based on the eligibility criteria retained, an additional CRF will have to be completed for all of the patients of a center. No random drawing will be carried out at this level. Approximately 570 patients received a treatment via lapatinib over the period of the study retained. Based on participation of 58 of the 81 centers that had requested a TUA, to which this study will be

	proposed, 330 completed dossiers can be expected.
Database objective	
Main objective	Describe the care pathways of patients with breast cancer who have received and/or are receiving treatment with lapatinib under Temporary Use Authorization (TUA)
Inclusion criteria	Patient who has received lapatinib for the treatment of breast cancer within the framework of a TUA between January 1, 2007 and 3 months prior to the beginning of the study
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)	2008
Date of last collection (YYYY or MM/YYYY)	2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	198
Data	
Database activity	Data collection completed

Type of data collected	Clinical data
Clinical data (detail)	Direct physical measures Medical registration
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	The investigating centers (prescribing doctor) that have accepted to carry out the study will receive a CRF for all of their patients eligible for the study: patient number, sex, age and treatment start date will be pre-completed in order to identify the patients. Prescribing doctors will complete the CRF using the medical doctor, based on the information available, and will return it to the logistics center
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Abstract (ISPOR 2009) Publication in progress
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only