PAMS - Multiple Morbidities for Elderly People with Breast Cancer

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General

Identification

Detailed name	Multiple Morbidities for Elderly People with Breast Cancer
Sign or acronym	PAMS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Demande CNIL en cours

General Aspects

Medical area	Cancer research Geriatrics
Health determinants	Genetic
Others (details)	Breast cancer
Keywords	Comorbidity, oncological therapeutic toxicities, geriatrics

Scientific investigator(s) (Contact)

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Unit	Unité d'Investigation clinique 19 ? Gérontologie Clinique
Organization	CHU de

Collaborations	
Funding	
Funding status	Public
Details	Recherche de financements en cours
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHU de Nantes
Organisation status	Public
Additional contact	
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 carried out as part of an interventional study	No
Additional information regarding sample selection.	In the absence of relevant literature data to support an effective calculation based on a numerical statistical hypothesis, no proposal for calculating minimum sample size. The size of the cohort was determined based on inclusion capacity during the last two years and monitoring by medical teams. 800 women are included. This number ensures a feasible study and the collection of maximum quality data.
Database objective	
Main objective	The main objective of the PAM study is to develop a prognostic score at 5-year survival for patients older than 65 years who have breast cancer. This score is calculated from breast cancer variables, medical, psychological and social characteristics, burden of morbidity, frailty and quality of life. Secondary objectives of the PAMS study are: - To investigate the influence of individually analysed

	geriatric parameters on choice of oncology treatment at 3 months. - To investigate the influence of quality of life on survival and the onset of toxicity at 3 months, 1 year and 5 years. To investigate the change in quality of life for patients at 3 months (immediately post-treatment), at 1 year (during chronic treatment and follow-up) and at 5 years. - To study changes in perception (Response Shift) over time through quality of life questionnaires, so as to distinguish between what is a change in perception and what is a change in quality of life when analysing changes in quality of life scores - To study the links between changes in perception over time through quality of life questionnaires and scores from Impact of Cancer questionnaires (IOC). - To evaluate the change in physical performance and autonomy in patients at 3 months, 12 months and 5 years. - To investigate the validity of the Lee Survival Score in this population at 5 years. - To investigate the geriatric and oncological parameters associated with sought medical healthcare, defined by unscheduled hospitalisation in the year following enrolment, at 3 months, 1 year and 5 years. - To assess the association between self-administered health questionnaires and geriatric evaluation parameters for this population. - To determine associations between prognostic score, onset of toxicity and oncology therapy at 5 years. - To determine associations between geriatric parameters, onset of toxicity and oncology therapy at 5 years. - To determine the most efficient comorbidity scale for estimating the tolerance to treatment offered to elderly people with breast cancer by stratifying tumour type and initial grade, as well as choice of treatment at 1 year.
Inclusion criteria	- Individuals over 65 years of age - Individuals diagnosed with breast cancer by anatomopathological confirmation - Individuals that have given written informed consent to participate in the study or informed consent by the person legally responsible. - Subjects covered by a social security scheme. - Subjects monitored by a cancer treatment centre or oncology service participating in the study.
Population type	
Age	Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population

Gender	Woman
Geography area	Regional
French regions covered by the database	Pays de la Loire
Detail of the geography area	- Patient enrolment will be carried out in two cancer treatment centres (the René Gauducheau Centre in Nantes and the Paul Papin Centre in Angers), and two university hospitals (Angers and Nantes).

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2014
Date of last collection (YYYY or MM/YYYY)	2021

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	800

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Biological data (detail)	Presence of hormone receptors, HER2 (membrane protein), SBR (Scarff Bloom and Richardson), and genomic criteria.
Presence of a biobank	Yes
Contents of biobank	Whole blood Others

Details of biobank content	--
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	An e-CRF will be designed by a data manager in accordance with protocol
Participant monitoring	Yes
Details on monitoring of participants	5 years
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only