- FREGAT

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General

Identification

Detailed name	FREGAT
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Accord CPP (10 décembre 2013) , ANSM (13 janvier 2014) ,CCTIRS (12 mars 2014) CNIL (23 décembre 2014)

General Aspects

Medical area	Cancer research
Health determinants	Iatrogenic Nutrition
Keywords	Tumour of the oesophagus, stomach tumour, diseases of the oesophagus, digestive system diseases, gastroesophageal cancer, digestive system, clinical and biological records, surgery

Scientific investigator(s) (Contact)

Name of the director	Mariette
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Organization	CHRU

Collaborations

Funding

Funding status	Public

Details	appel à projet INCa 2012
Governance of the database	
Sponsor(s) or organisation(s) responsible	CHRU Lille
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	Yes
Details	Performed at individual level
Additional information regarding sample selection.	All newly diagnosed patients in participating centres with gastro-oesophageal treatment-naive cancer will be included after acceptance and signed consent, whether they undergo surgery or not, regardless of histological type, tumour stage or therapeutic strategy. Exclusion criteria: - Men or women under the age of 18. - People deprived of liberty or under guardianship (including temporary guardianship). - People who do not speak French. - Adults unable to express their consent. - Patients already included in the FREGAT database. - Patients who refuse to participate.
Database objective	
Main objective	Main Objective: To identify, through the creation of a clinico-biological, prospective, multicentric French database, the clinical, biological and tumour factors linked to anti-tumour therapy resistance in patients treated for stage I to IV oesophageal or stomach cancer. Secondary Objectives: - To assess the impact of different current therapeutic strategies for recurrence, survival and quality of life. - To identify predictive factors for patient treatment

	resistance in order to identify the most efficient and least toxic therapeutic combination. - To describe individual, social and behavioural characteristics of patients included in the study. - To identify individual and collective determinants that influence possible access to care and initiation of treatment. - To identify new prognostic and predictive relapse factors.
Inclusion criteria	- Men or women ? 18 ans. - Presenting with oesophageal or gastro-oesophageal junction carcinoma recently diagnosed by biopsy, regardless of cancer subtype, tumour stage or proposed treatment. - Treatment-naive cancer. - Have given clear and written consent for blood samples, various questionnaires and the collection of patient information. N.B.: Patients participating in a clinical trial can be included in the FREGAT trial. There is no exclusion period.

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	Male Woman
Geography area	National
Detail of the geography area	Metropolitan France (33 centres, 46 teams)

Data collection

Dates

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

Size of the database

Size of the database (number of individuals)	Greater than 20 000 individuals
Details of the number of individuals	135 patients au 20/01/2015

Data

Database activity	Current data collection
Type of data collected	Clinical data Declarative data Biological data Administrative data
Clinical data (detail)	Direct physical measures Medical registration
Declarative data (detail)	Paper self-questionnaire
Biological data (detail)	- a collection of tumour samples (pre-treatment biopsies. post-treatment biopsies, surgical specimens) collected in accordance with current quality charters. These samples will be stored in the corresponding investigation centre. Samples will ideally be frozen. However, paraffin conservation will also be acceptable. - blood sample collection to be put in place in 6 centres with high recruitment potential that have a Biological Resource Centre (CRB) (approximately 3,000 patients). These approved CRBs will ensure sample quality control as per usual.
Administrative data (detail)	The investigating party will issue the patient a FREGAT cohort registration form to be completed by the patient and posted to the Caen Cancéropôle Nord-Ouest Data Processing Centre (CTD/CNO).
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma Tissues
Details of biobank content	Consult the scientist in charge (Professor Christophe MARIETTE)
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Other (detail)	socio-economic questionnaire.

Procedures	
Data collection method	The collection of clinical, biological and epidemiological data as well as the characteristics of patient treatment will be stored in the electronic case report form (e-CRF) for the study
Participant monitoring	Yes
Details on monitoring of participants	Follow-up for 3 years after inclusion. All information in the database is gathered during patient clinical follow-up, according to usual visit and follow-up practices in each investigating centre. Annual updates to information is required systematically. Updates to information regarding events such as death or recurrence will be also required.
Links to administrative sources	Yes

Promotion and access

Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/25062398
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/25012732
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/24919373
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/24075273
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/23313257
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/23064779
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/22005144

Access	
Terms of data access (charter for data provision, format of data, availability delay)	Publication or presentation of results from this trial is not permitted without prior agreement from the sponsor (CHRU de Lille) and coordinating researcher (Prof. Christophe MARIETTE).
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only