

GFPC 08-05 - Longitudinal Study of Elderly Patients with Small Cell Lung Cancer: Standardised Geriatric Assessment and Postoperative Morbidity Following Lung Resection,

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General

Identification

Detailed name	Longitudinal Study of Elderly Patients with Small Cell Lung Cancer: Standardised Geriatric Assessment and Postoperative Morbidity Following Lung Resection,
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Sign or acronym	GFPC 08-05
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CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL 08755 (16/10/2008), CPP ILE DE FRANCE V
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General Aspects

Medical area	Cancer research Geriatrics
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Health determinants	Nutrition Social and psychosocial factors
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Keywords	OPERABLE NON-SMALL CELL LUNG CANCER - GERIATRIC ASSESSMENT- SUBJECTS OVER 70 YEARS OLD
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Scientific investigator(s) (Contact)

Name of the director	Raynaud
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Surname	Christine
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Organization	GROUPE FRANCAIS DE PNEUMO CANCEROLOGIE - GFPC- ASSOCIATION LOI 1901
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Organization	GROUPE FRANCAIS DE PNEUMO CANCEROLOGIE - GFPC - ASSOCIATION LOI 1901
Collaborations	
Funding	
Funding status	Private
Details	GFPC study sponsored by the Groupe Français de Pneumo Cancérologie (French Pneumo-Oncology Group) - Association under 1901 law -
Governance of the database	
Sponsor(s) or organisation(s) responsible	GFPC - GROUPE FRANCAIS DE PNEUMO CANCEROLOGIE
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 consists of consecutive enrolment of

sample selection.

patients that fulfil the inclusion criteria throughout all GFPC centres, subject to obtaining their consent.

Database objective

Main objective	To test the hypothesis that standardised geriatric assessment is a prognostic factor for post-operative complications within 30 days following surgical resection for lung cancer.
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Inclusion criteria	Patients over 70 years old with suspected NSCLC at clinical stage I to IIIB with indication of curative surgical resection considered by multidisciplinary meeting.
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Population type

Age	Elderly (65 to 79 years) Great age (80 years and more)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	62 French Pneumo-Oncology Group sites throughout France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
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Date of last collection (YYYY or MM/YYYY)	03/2014
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	300
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Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data Paraclinical data Biological data Administrative data
Clinical data (detail)	Direct physical measures
Details of collected clinical data	Pre-operative data, peri-operative data and post-operative and hospitalisation data at 30 days following operation
Declarative data (detail)	Paper self-questionnaire Face to face interview
Details of collected declarative data	EGS, Spitzer Index, HCCA
Paraclinical data (detail)	Lifestyle
Biological data (detail)	peri-operative biological data
Administrative data (detail)	Demographic data
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
Procedures	
Data collection method	Data are collected in an electronic case report form collected by each centre through a dedicated database.
Quality procedure(s) used	Kick-off meeting, consistent data in computerised database.
Participant monitoring	Yes
Details on monitoring of participants	+30 days post-operative data.
Links to administrative sources	No
Promotion and access	
Promotion	
Access	

Terms of data access (charter for data provision, format of data, availability delay)	Data are collected by the researcher from the medical record of the patient who gave their consent through the electronic case report form. Each researcher can only access data from their centre with a password that is changed every 2 months. Data are stored on the B&D company server. Analysis will be carried out using SAS software. A data CD will be retained by the main researcher and GFPC headquarters for 15 years.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only