

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,

Sign or acronym GFPC 08-05

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

General Aspects

Medical area Cancer research
Geriatrics

Health determinants Nutrition
Social and psychosocial factors

Keywords OPERABLE NON-SMALL CELL LUNG CANCER - GERIATRIC ASSESSMENT- SUBJECTS OVER 70 YEARS OLD

Scientific investigator(s) (Contact)

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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.

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.

Population type

Age 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 62 French Pneumo-Oncology Group sites throughout France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2009

Date of last collection (YYYY or MM/YYYY) 03/2014

Size of the database

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

Details of the number of individuals 300

Data

Database activity Data collection completed

| | |
|---------------------------------------|--|
| 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