COLT - Cohort in lung transplantation

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Last update : 06/12/2013 | Version : 2 | ID : 60154

| General | |
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| Identification | |
| Detailed name | Cohort in lung transplantation |
| Sign or acronym | COLT |
| CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation | CNIL : 911142 ; CPP n°2009-R4 le 24/02/2009 ; Afsapps : B90121-60 |
| General Aspects | |
| Medical area | Pneumology |
| Pathology (details) | Lung transplantation |
| Health determinants | Genetic |
| Keywords | Lung Transplantation, Chronique Lung Allograft dy |
| Scientific investigator(s) (Contact) | |
| Name of the director | Magnan |
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| Unit | L'INSTITUT DU THORAX - INSERM UMR1087 / CNRS UMR 6291 |
| Organization | INSERM / CHU DE |
| Collaborations | |
| Participation in projects, networks and consortia | Yes |

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Participation to the SysCLAD European ProjectParticipation to the ENCE network

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| Funding | |
| Funding status | Mixed |
| Details | PHRC NATIONAL 2009 ASSOCIATION VAINCRE LA MUCOVISCIDOSEAGENCE DE BIOMEDECINEINSERM RESEAUX |
| 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. | Prospective cohort |
| Database objective | |
| Main objective | Highlight preditive factors of the occurrence of chronic lung allograft dysfunction by immunologic, transcriptomics, genomics and proteomics approaches applied to blood and in situ samples performed on patients. |
| Inclusion criteria | Men and women aged over 18 years who are on the waiting list for lung or cardiopulmonary transplantation or included the day of transplantation, and who give their written inform consent. |

| Population type | |
|---|--|
| Age | Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) |
| Population covered | Sick population |
| Gender | Male Woman |
| Geography area | International |
| Detail of the geography area | Multicentric cohort including the 11 French centers for transplantation and the Erasme center in Brussels (Belgium) |
| Data collection | |
| Dates | |
| Date of first collection (YYYY or MM/YYYY) | 09/2009 |
| Date of last collection (YYYY or MM/YYYY) | 09/2017 |
| Size of the database | |
| Size of the database (number of individuals) | [500-1000[individuals |
| Details of the number of individuals | 1000 patients included pre-transplantation, from which 750 transplanted patients |
| Data | |
| Database activity | Current data collection |
| Type of data collected | Clinical data Biological data |
| Clinical data (detail) | Direct physical measures Medical registration |
| Details of collected clinical data | Clinical examination before trnasplantation and post-transplantaiton every 6 months. Data collected : medical history, concomitant medications, bacterial and viral colonization, episodes of rejection, infections, respiratory function, transplantation complication, immunology, survival |

| Biological data (detail) | A each visit, blood sample for immunological, genomic, and transcriptomic analysis will be collected. According to practices of each centers, induced sputum, Exhaled Air Condensate will also be collected. Broncho Alveolar fuids and transbronchial biopsies will be collected according to the habits of each center. |
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| Presence of a biobank | Yes |
| Contents of biobank | Whole blood Serum Plasma Blood cells isolated Fluids (saliva, urine, amniotic fluid, ?) DNA DNAc/RNAm Others |
| Details of biobank content | Biobank: Plasma Bank, Serum Bank, PBMC DNA, RNA, transbronchial biopsy, supernatant of induced sputum, exhaled air condensate, broncho-alveolar liquid |
| Health parameters studied | Health event/morbidity Health event/mortality |
| Procedures | |
| Data collection method | Manual entry of information collected during medical examination from paper questionnaires, clinical examinations with double input: Direct input Laboratory tests: direct entry |
| Participant monitoring | Yes |
| Details on monitoring of participants | 5 years follow-up |
| Links to administrative sources | Yes |
| Linked administrative sources (detail) | Agence de Biomedecine Database. Exchanges twice a year |
| Promotion and access | |
| Promotion | |
| Link to the document | <u>http://www.ncbi.nlm.nih.gov/pubmed/?</u> <u>term=COLT+AND+Magnan+A[author]</u> |
| Description | List of publications in Pubmed |
| | |

Access

| Terms of data access (charter for data provision, format of data, availability delay) | Possible data use by academic teams via approval of the Scientific Council of the cohort. Data can be used by industry via approval of the Director commitee of the cohort. |
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| Access to aggregated data | Access on specific project only |
| Access to individual data | Access on specific project only |