

RaDiCo-PID - Idiopathic Interstitial Pneumonia: From Infancy to Elderly

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Last update : 12/03/2024 | Version : 2 | ID : 73380

General	
Identification	
Detailed name	Idiopathic Interstitial Pneumonia: From Infancy to Elderly
Sign or acronym	RaDiCo-PID
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS n° 16.050Bis / CNIL Decision n° DR-2016-431
General Aspects	
Medical area	Pediatrics Pneumology Radiology and medical imaging Rare diseases
Study in connection with Covid-19	No
Pathology (details)	Idiopathic Interstitial Pneumonia: Idiopathic Interstitial Pneumonia (IIP), known in French as ? Pneumopathies Interstitielles Diffuses (PID)? and referred in the current protocol as IPP/PID, encompass a group of diffuse infiltrative lung diseases of unknown origin that affect the lung architecture and are characterized by a progressive and often irreversible remodeling of the lung. Clinical expression includes mainly dyspnea, restriction on pulmonary function testing, impaired haematosis and radiologic diffuse lung infiltration. In most situations, these diffuse lung disorders are chronic, with high morbidity and mortality due to the lack of curative therapy.
Health determinants	Climate Genetic Healthcare system and access to health care services Lifestyle and behavior Medicine

Occupation
Pollution
Social and psychosocial factors

Scientific investigator(s) (Contact)

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Organization	French National Institute for Health and Medical Research (Inserm)

Collaborations

Participation in projects, networks and consortia	Yes
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Details	Rare Pulmonary Diseases Healthcare Network RespiFil / European Reference Network ERN-LUNG
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Funding

Funding status	Mixed
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Details	Funded by the French « Investissements d'Avenir » cohorts programme, Grant « ANR » 10-COHO- 0003. This study is also supported by industrial funding within the framework of a public-private partnership.
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Governance of the database

Sponsor(s) or organisation(s) responsible	French National Institute for Health and Medical Research (Inserm)
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Organisation status	Public
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Presence of scientific or steering committees	Yes
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Labelling and database evaluation	Security audit certification of the database
Additional contact	
Main features	
Type of database	
Type of database	Morbidity registers
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is made on the basis of:	Another treatment or procedure
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	The goal of the IIP/PID cohort is to include prevalent and incident IIP/PID cases diagnosed in paediatric patients and adult patients. For the prevalent cases and the retrospective nature of the data, a diagnosis validation will be required. Paediatric patient population Paediatric IIP/PID patients include all patients with diffuse parenchymal diseases linked to rare conditions others than immune deficiencies, proliferative disorders, metabolic disorders, and drug toxicity. Since the first description of the RespiRare IIP/PID paediatric cases, almost 400 patients (prevalent cases) have been included in the database. Around 60-80 new IIP/PID cases (incident cases) are currently reported per year. However, this number is underestimated, and will most likely increase with the identification of more adapted diagnostic criteria. Adult patient population For IIP/PID patients with IPF (approximately two thirds of the IIP/PID adult patients): considering the relatively large number of patients mainly aged and with a very poor prognosis, only prospective data will be collected to maximize the longitudinal collection of data and allow a detailed and accurate description of disease evolution in this population. For IIP/PID patients without IPF but with diffuse parenchymal diseases linked to rare conditions others than immune deficiencies, proliferative

disorders, metabolic disorders, and drug toxicity (approximately one third of the IIP/PID adult patients): IIP/PID, incident cases and prevalent cases (with retrospective data) will be included in the cohort.

About 2000 adult IIP/PID patients are expected to be recruited during this study.

Database objective

Main objective

Primary Objective

The main objective is to describe the phenotypic features of the paediatric and adult patients with IIP/PID, at diagnosis and during the follow-up. These data will be critical for the description of the natural history of the various forms of IIP/PID.

Secondary Objectives

The secondary objectives are to:

- ? Identify gene factors involved in disease initiation and progression,
- ? Investigate the extent to which environmental and co-morbidity factors may influence disease severity and outcome
- ? Identify and validate biomarkers for disease diagnosis and progression

Exploratory objectives

- ? Production of improved strategies for patient recruitment and enrolment into clinical trials
- ? Development of novel strategy for patient follow-up
- ? Development of novel diagnostic approaches
- ? Evaluation of effect on natural history of disease, and tolerance of therapy, in a large population in real life
- ? Development of novel therapeutic approaches

Information Technology Objectives

- ? Develop and diffuse an electronic tool of data collection from various sources linked to a database integrating a system of management and follow-up of data-management allowing collection of data for IIP/PID paediatric and adult patients.
- ? Include data generated by patients and, where relevant, their parents and/or carers.

Inclusion criteria

Patient with a diagnosis of IIP/PID

IIP/PID diagnosis is established on presenting history, clinical, radiological and functional and if available pathological findings. Inclusion criteria include:

Clinical criteria: chronic respiratory insufficiency

manifestations including dyspnea/tachypnea, cough, and cyanosis during exercise or at rest
 Radiological criteria: characteristic chest High-Resolution Computed Tomography (HRCT) abnormalities including widespread ground glass or alveolar attenuation, reticulation often associated with traction bronchiectasis, and honeycombing
 Functional criteria: pulmonary function test abnormalities reflecting a restrictive pattern and including: loss of lung volume, vital capacity (VC), total lung capacity (TLC); reduction in the diffusion capacity of the lung for carbon monoxide (DLCO), gas exchange abnormalities, and altered ventilatory response to exercise
 Patients (parents/guardians for paediatric/patients) having given an informed consent to participate in the protocol
 Patients affiliated to the ?Regime National d'Assurance Maladie?

Non-inclusion Criteria

Patients with diffuse parenchymal lung diseases caused by drug toxicity, immunodeficiency, proliferative disorders including histiocytosis, and metabolic disorders
 Patients (parents/guardians for paediatric patient) not able to approve/understand the protocol

Population type

Age
 Newborns (birth to 28 days)
 Infant (28 days to 2 years)
 Early childhood (2 to 5 years)
 Childhood (6 to 13 years)
 Adolescence (13 to 18 years)
 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

Pathology J84 - Other interstitial pulmonary diseases

Gender Male
 Woman

Geography area National

Detail of the geography area Complete national coverage through the network of rare pulmonary disease reference and competence

centers

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2017

Date of last collection (YYYY or MM/YYYY) 2021 minimum

Size of the database

Size of the database (number of individuals) [1000-10 000[individuals

Details of the number of individuals 2550

Data

Database activity Current data collection

Type of data collected
Clinical data
Declarative data
Paraclinical data
Biological data

Clinical data (detail)
Direct physical measures
Medical registration

Details of collected clinical data
The main variables collected include demographic aspects, family history, clinical examination results, environmental data, socio-professional details, patients' medical history, anatomopathological characteristics, biological, microbiological, and imaging tests. Both studies also involve bronchoscopic procedures, respiratory function measurements, disease progression monitoring, fertility data collection, genetic aspects, treatment records, quality of life questionnaires, and the inclusion of information on the Covid-19 episode.

Declarative data (detail)
Paper self-questionnaire
Internet self-questionnaire
Face to face interview

Details of collected declarative data
SF36 or SF10 + St George's Hospital

Biological data (detail)
Record of biological results (hematology, biochemical, immunity, serology); Record of results

for: bacteriology, virology, parasitology, mycology, bronchoscopy, bronchoalveolar lavage examination; Record of lung function tests, arterial blood gas and spirometry (If available sleep gas exchange and polysomnography); If available/performed, records of results for lung tissue examination, lung biopsy (surgical, transbronchial), lung explant; If available/performed, records of other organ function evaluation (including digestive and cardiac examinations)

Presence of a biobank

Yes

Contents of biobank

Serum
Fluids (saliva, urine, amniotic fluid, ?)
Tissues
DNA
Others

Details of biobank content

plus broncho alveolar liquids

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

Quality of life/perceived health (detail)

SF36 or SF10 + St George's Hospital

Procedures

Data collection method

eCRF using REDCap; Cloud based, secure by design, web accessible platform. Certified Health Data Hosting resource

Classifications used

HPO, ICD10, Snomed CT, Orpha Codes and ORDO, Drug dictionary (DCIs)

Quality procedure(s) used

Continuous data management; Data Management Plan and Data Validation Plan. Native controls and Query system

Participant monitoring

Yes

Monitoring procedures

Monitoring by convocation of the participant
Monitoring by contact with the referring doctor
Monitoring by crossing with a medical-administrative database

Links to administrative sources	No
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Promotion and access

Promotion

Access

Presence of document that lists variables and coding procedures	Yes
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Terms of data access (charter for data provision, format of data, availability delay)	Access requests to RaDiCo-PID data (rough / structured), biocollections or to analytic reports will be examined by the scientific committee following submission of a Specific Research Project (SRP) synopsis, as defined in the Resource Access Charter. Must be sent to pid@radico.fr
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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