COBRA - Asthma and Airway Obstruction Cohort: Clinicobiological Cohort Follow-up

Head :Aubier Michel, Université Paris 7, APHP, Inserm U 700

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General

Identification

Detailed name	Asthma and Airway Obstruction Cohort: Clinicobiological Cohort Follow-up
Sign or acronym	COBRA
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 28/01/2008

General Aspects

Medical area	Pneumology
Health determinants	Climate Pollution
Keywords	Health episodes, severity

Scientific investigator(s) (Contact)

Name of the director	Aubier
Surname	Michel
Address	Hôpital Bichat, 46 rue Henri Huchard 75018 PARIS
Phone	+33 (0)1 40 25 68 00
Email	michel.aubier@bch.aphp.fr
Unit	Université Paris 7, APHP, Inserm U 700
Organization	INSERM

Collaborations

Funding

Funding status	Mixed
Details	Inserm, CHU de Nîmes, LEGS POIX, GSK, AstraZeneka, Chiesi
Governance of the database	
Sponsor(s) or organisation(s) responsible	Institut National de la Santé et de la Recherche Médicale
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 Closing date for inclusion: end of 2014 Other bodies active in creating this cohort: CHU, CHG
Database objective	
Main objective	General objective: to establish a biological resource centre (serum, DNA) for two cohorts of patients with asthma and COBP monitored over a 10 year period. Secondary objective: to discover biological markers of severity (using proteomics technology) and genetic risk factors (by genomic-based approaches) associated with the evolution of these pathologies.
Inclusion criteria	Two cohorts: one with asthmatics and one with individuals affected by COBP; subjects included between the ages of 18 and 80 years old. Asthma cohort: including patients who are non-smokers and smokers with compatible clinical history and individuals with a reversible obstructive airway disease, based on a FEV1/CV <75% and an FEV1 baseline value improvement of 12% or 200 ml after inhalation of 400 µg of Salbutamol. COBP cohort:

	including patients who are smokers (>10 packets per year) presenting with an obstructive airway disease (FEV1/CV <75%) and an FEV1 improvement of less than 10% after inhalation of 200 µg of Salbutamol.
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	National
Detail of the geography area	Multicentric cohort throughout France (15 centres)
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	03/2008
Date of last collection (YYYY or MM/YYYY)	03/2018
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	- 1000 asthmatiques - 500 BPCO
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	<Clinic: relevant personal and familial medical history (Asthma cohort: eczema, asthma, rhinoconjunctivitis; COPD cohort: asthma, chronic bronchitis, emphysema, respiratory insufficiency), complete physical examination. Therapeutic: concomitant medication. Quality of life: patient is to be questioned regarding quality of life with a validated Juniper questionnaire (Asthma cohort)
Declarative data (detail)	Paper self-questionnaire
Details of collected declarative data	Demographic: initials, date of birth, sex, geographic origin, professional activity. Risk factors: smoking
Paraclinical data (detail)	Imaging: chest x-ray, CT scan for COBP EFR, allergy tests, bronchial fibroscopy for a sub-group of patients (2 centres).
Biological data (detail)	Type of samples taken: Blood and serum
Presence of a biobank	Yes
Contents of biobank	Serum DNA
Details of biobank content	Serum bank, DNA bank
Health parameters studied	Health event/morbidity Health event/mortality Quality of life/health perception
Quality of life/perceived health (detail)	Quality of life: patient is to be questioned regarding quality of life with a validated Juniper questionnaire (Asthma cohort)

Procedures

Data collection method	Self-administered questionnaire: manual input Interview: manual input Clinical examinations: manual input Biological analysis: manual input
Participant monitoring	Yes
Details on monitoring of participants	Duration of follow-up per patient: individuals are monitored over a period of ten years after selection, with one visit every six months during the first five years, followed by every year for the next five years.
Links to administrative sources	No

Promotion and access

Promotion	
Link to the document	Cobra.pdf
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams Contractual access subject to COBRA Scientific Council validation. Research projects that can use clinical and/or biological cohort data are encouraged and validated by the Scientific Council (2 members per centre). Data may not be used by industrial teams.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only