METABOL - Cohort of Patients Fulfilling at Least One Metabolic Syndrome Criterion

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General

Identification

Detailed name	Cohort of Patients Fulfilling at Least One Metabolic Syndrome Criterion
Sign or acronym	METABOL
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL no. : 117 48 22 (MR001/08/06/2006); AFFSAPS : no. 2009-A00857-50 (24/09/2009); CPP Ouest II : no. 2009-18 (01/12/2009)

General Aspects

Medical area	Endocrinology and metabolism
Health determinants	Nutrition
Keywords	factor, prospective, complication, relationship, assessment

Scientific investigator(s) (Contact)

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Unit	INSERM U1063 - Stress Oxydant et Pathologies Métaboliques
Organization	INSERM - Institut National de la Santé et de la Recherche

Name of the director	Boursier
Surname	Jérôme

Collaborations

Funding

Funding status	Public
Details	2008 Pays-de Loire Regional Call for Projects.

Governance of the database

Sponsor(s) or organisation(s) responsible	INSERM - 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.	Active patient population undergoing metabolic and vascular assessment at the Cross-Sectional Nutrition Unit of Angers UHC. The active patient population consists of consecutive subjects admitted as outpatients and fulfilling at least one metabolic syndrome criterion.

Database objective

Main objective	Main aim: to prospectively assess the role of hepatic steatosis in the onset of a metabolic syndrome (MS) and disorders linked to the kidney disease/MS combination Secondary objectives: - To measure the chief complication of hepatic

	steatosis, i.e. liver fibrosis; and to study the connection to MS, non-alcoholic fatty liver disease (NAFLD) and sleep apneoa syndrome (SAS). - To determine whether blood tests established for the non-invasive diagnosis of liver damage (steatosis, inflammation, liver fibrosis) in dysmetabolic liver disease also have prognostic value and may identify patients at risk of cardiovascular complications, malignancies, diabetes, or SAS.
Inclusion criteria	Patients aged between 18 and 65 years old, with non-alcoholic fatty liver disease (NAFLD) and/or diabetes and/or sleep apnoea.
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	General population
Gender	Male Woman
Geography area	Local
French regions covered by the database	Pays de la Loire
Detail of the geography area	3 departments in Angers UHC (Endocrinology-Nutrition, Gastroenterology and Pulmonology).
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	01/2010
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	237
Data	
Database activity	Current data collection

Type of data collected	Clinical data Declarative data
Clinical data (detail)	Medical registration
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality

Procedures

Data collection method	Data collected by the CRA recruited for the project at the time of outpatient hospitalisation. The CRA enters the data in a secure file (Epidata) that belongs to the hospital's clinical research centre.
Participant monitoring	Yes
Details on monitoring of participants	Follow-up visit every 3 years for 12 years.
Links to administrative sources	No

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Publications. The epidata is transferred to Excel and checked by our data manager at the hospital's clinical research center. Access is limited to members of the METABOL cohort scientific committee.
Access to aggregated data	Access on specific project only
Access to individual data	No access