

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

Head :Ramaroson Andriantsitohaina, INSERM U1063 - Stress Oxydant et Pathologies Métaboliques  
Boursier Jérôme

Last update : 05/23/2013 | Version : 1 | ID : 5287

## 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)

Name of the director Ramaroson

Surname Andriantsitohaina

Address IBS Institut de Biologie en Santé Allée du Pont CHU d'Angers 4 rue Larrey 49933 Angers Cedex 9

Phone +33 (0)2 44 68 85 80

Email ramaroson.andriantsitohaina@univ-angers.fr

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
<b>Collaborations</b>	
<b>Funding</b>	
Funding status	Public
Details	2008 Pays-de Loire Regional Call for Projects.
<b>Governance of the database</b>	
Sponsor(s) or organisation(s) responsible	INSERM - Institut National de la Santé et de la Recherche Médicale
Organisation status	Public
<b>Additional contact</b>	
<b>Main features</b>	
<b>Type of database</b>	
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.
<b>Database objective</b>	
Main objective	<p>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</p> <p>Secondary objectives:</p> <ul style="list-style-type: none"> <li>- To measure the chief complication of hepatic</li> </ul>

steatosis, i.e. liver fibrosis; and to study the connection to MS, non-alcoholic fatty liver disease (NAFLD) and sleep apnea 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.
<b>Population type</b>	
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).
<b>Data collection</b>	
<b>Dates</b>	
Date of first collection (YYYY or MM/YYYY)	01/2010
<b>Size of the database</b>	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	237
<b>Data</b>	
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
<b>Procedures</b>	
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
<b>Promotion and access</b>	
<b>Promotion</b>	
<b>Access</b>	
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