OBEMASCH - Massive Obesity and Surgery: Referral Centre Cohort for Medical and Surgical Inpatient Treatment for Massive Obesity

Head :Basdevant Arnaud, INSERM U872 (EQUIPE 7) Centre de recherche en nutrition humaine Ile de FranceCentre de référence APHP pour la prise en charge médicale et chirurgicale de l'obesité CRMOPIERRE ET MARIE-CURIE-PARIS 6, HOPITAL PITIE-SALPETRIERE
Clément Karine, EQ 7 INSERM U 872 CR CORDELIERS CENTRE DE RECHERCHE EN NUTRITION HUMAINE ILE DE FRANCE INSERM UP6

Last update : 07/22/2014 | Version : 3 | ID : 60103

General

Identification

Detailed name	Massive Obesity and Surgery: Referral Centre Cohort for Medical and Surgical Inpatient Treatment for Massive Obesity
Sign or acronym	OBEMASCH
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL : 27/03/2007

General Aspects

Medical area	Endocrinology and metabolism
Health determinants	Genetic Iatrogenic Nutrition
Keywords	medical assessment, determinants, somatic, biological, psychological, metabolic, social, consequences, cardiovascular, respiratory, complications, deficiencies, oral dental condition, nutritional assessment, evaluation, health events

Scientific investigator(s) (Contact)

Name of the director	Basdevant
Surname	Arnaud
Address	75013 PARIS
Phone	+ 33 (0)1 42 17 77 17

Email	arnaud.basdevant@psl.aphp.fr
Unit	INSERM U872 (EQUIPE 7) Centre de recherche en nutrition humaine Ile de FranceCentre de référence APHP pour la prise en charge médicale et chirurgicale de l'obesité CRMOPIERRE ET MARIE-CURIE-PARIS 6, HOPITAL PITIE-SALPETRIERE
Organization	APHP
Name of the director	Clément
Surname	Karine
Email	karine.clement@psl.aphp.fr
Unit	EQ 7 INSERM U 872 CR CORDELIERS CENTRE DE RECHERCHE EN NUTRITION HUMAINE ILE DE FRANCE INSERM UP6
Organization	APHP

Collaborations

Participation in projects, networks and consortia	Yes
Details	Enrolment in a European project: HEPADIP AND ADAPT
Others	Other associated cohorts: current discussions with European teams (Switzerland, Italy, Sweden) involved in this type of surgery and patient monitoring.

Funding

Funding status	Mixed
Details	Resources are mainly public. However, private input was obtained on an ad hoc basis as part of the programme on changes in metabolism - APHP (DRC) - Ile de France Human Nutrition Research Centre (CRNH) - ALFEDIAM/AFERO - ANR - Inserm/UPMC (PROVISIONS) - METABOMICS (BERLIN, GERMANY)

Governance of the database

Sponsor(s) or organisation(s) responsible	APHP

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	Yes
Details	Performed at individual level
Additional information regarding sample selection.	Prospective

Database objective

Main objective	General objective: to monitor variations in weight and body composition as well as metabolic, cardiovascular and pulmonary comorbidities introduced by surgery for obesity. Secondary objective: to study tissue, vitamin, cellular and systemic physiopathological changes (metabolic and inflammatory phenomena, insulin resistance) induced by bariatric surgery.
Inclusion criteria	Patients diagnosed as massively obese (BMI greater than 40 kg/m²) or severely obese (BMI between 35-40 kg/m²) with comorbidities (diabetes, sleep apnoea syndrome, arterial hypertension etc.) and whose weight is stable or has increased over a 3 month period (weight change of at least 2 kg) preceding gastric surgery (bypass, sleeves, ring), after a decision made by a multi-disciplinary team and medical follow-up for at least one year. Between 18 and 55 years of age.

Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
Population covered	Sick population

Gender	Male Woman
Geography area	Regional
French regions covered by the database	Île-de-France
Detail of the geography area	Ile de France: a study on geographical origin of patient enrolment shows that 25% of patients come from central Paris. The other part mainly comes from the Paris Basin. The other portion mainly originates from the Paris Basin.

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	01/2002

Size of the database

Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	479 (depuis/since 2002)

Data

Database activity	Data collection completed
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	- Family history (obesity, diabetes, cardiovascular disease); - Personal weight history; - anthropometric parameters (weight, height, BMI, waist circumference, hip and neck measurements); - assessment of comorbidities (diabetes, dyslipidemia, cardiovascular, hypertension, respiratory, articular); - Oral and gastric assessment; - nutritional assessment; - treatment; - adverse events (surgical complications).
Declarative data (detail)	Paper self-questionnaire

	Face to face interview
Details of collected declarative data	Self-administered questionnaire at follow-up (TO, T3, T6 T12) Information collected by self-administered questionnaire: - Quality of life (SF 36 - Physical activity (Baecke) - alcohol and tobacco consumption, eating behaviour (TFEQ) - fatigue score and depression scale (Beck) - Epworth Scale (sleepiness), pain - Sandvik score (urinary incontinence) Interview questionnaire at baseline and during follow-up (TO, T3, T6, T12, every year) Information collected during interview: - socioeconomic status - dietary assessment (qualitative and quantitative input) - psychological assessment - clinical assessment - comorbidity assessment
Paraclinical data (detail)	Imaging
Biological data (detail)	Type of samples taken: usual tests (complete blood count, electrolytes, free fatty acids and glycerol, liver function test, lipid profile, fasting glycaemia, HbA1c, serum calcium, thyroid function, vitamin assessment, calcium-phosphate product, albumin, pre-albumin, orosomucoid, fibrinogen, iron status, zinc, selenium) corpus. Induced changes in levels of leptin, ghrelin, insulin, adiponectin, interleukin-6) DNA research (MC4R gene mutation). Urine sample (microalbuminuria, calcium-phosphate product). Adipose tissue celluarity and anatomical pathology (liver, adipose tissue).
Presence of a biobank	Yes
Contents of biobank	Serum Plasma Tissues DNA
Details of biobank content	Serum bank, Plasma bank, DNA bank, adipose, liver, intestine and muscle tissue
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption

Procedures

Data collection method	Self-administered questionnaire: entry from paper questionnaire Clinical examinations: direct input Biological analysis: direct input
Quality procedure(s) used	Request for consistency after data is processed electronically. Missing data is managed by returning to source record or third party. Physicians contacted again for follow-up visits Subjects contacted again for follow-up visits Internal quality audits carried out once per month as part of the CRC An APHP audit was carried out in 2007 on the database from 2005 Other quality procedure(s): a systematic return and verification of source data is carried out by the researcher with contact from physician collecting the clinical and laboratory data during data analysis as part of the studies conducted by the INSERM team. Aberrant laboratory values are verified from source data Patients are informed of the use of their data
Participant monitoring	Yes
Details on monitoring of participants	before surgery, 1 month, 3 months, 6 months, 1 year and then every year during clinical assessment
Links to administrative sources	Yes
Linked administrative sources (detail)	PMSI, Pathology register

Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Data may be used by academic teams Access conditions: several hospitals and research teams are interested in kinetic evolution of comorbidities using the bypass model; many specialities are involved and several collaborations are taking place, such as: - Bone characteristics study (bone remodelling factors) Dr. Richette's rheumatology department hospital team, Lariboisiere - post- and pre-operative masticatory characteristics study (Bretonneau hospital, Dr. Miller) - intestinal flora study (Dr. Joel Dore and Dr. Corthier) or within the European programme framework (ADAPT, HEPADIP) All studies are subject to CPP (Ethics Committee) review and specific funding. Bioresource usage is subject to MTA (material transfer agreement) with APHP Data may be used by industrial teams Access conditions: Specific

	APHP or INSERM industry contracts A contract was established in 2006 with Berlin Metabomics to investigate metabolic evolution
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only