OPAL - Cross-sectional study assessing the prevalence of co-addictions in subjects receiving opioid substitution treatment: determination of the clinical and pharmacological profile

Head :Grall-Bronnec Marie, Addiction department of the CHU de Nantes / UIC 18 Clinical Investigation Unit: Behavioural addictions and complex mood disorders / EA 4275 SPHERE

Last update : 02/17/2020 | Version : 1 | ID : 73282

General

Identification

Detailed name	Cross-sectional study assessing the prevalence of co-addictions in subjects receiving opioid substitution treatment: determination of the clinical and pharmacological profile
Sign or acronym	OPAL
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL: authorisation No. 913237 / CCTIRS: No. 13.223

General Aspects

Medical area	Biology Psychology and psychiatry
Health determinants	Addictions Genetic
Keywords	Opioid dependence, opioid substitution treatment, psychoactive substance, pharmacokinetics, pharmacogenetics, polymorphism, cytochrome P450 2D6, addictions, pathological gambling

Scientific investigator(s) (Contact)

Name of the director	Grall-Bronnec
Surname	Marie
Address	IFAC Batiment Louis Philippe Hopital St Jacques 85 rue St Jacques 44 093 Nantes cedex 01
Phone	+ 33 (0)2 40 84 61 16

Email	marie.bronnec@chu-nantes.fr
Unit	Addiction department of the CHU de Nantes / UIC 18 Clinical Investigation Unit: Behavioural addictions and complex mood disorders / EA 4275 SPHERE
Organization	Chu de Nantes

Collaborations

Participation in projects, networks and consortia	Yes
Details	Multicentric study in collaboration with the CHU de Brest, CHU d'Angers, CH de Morlaix, CH G. Régnier de Rennes, CSAPA "Le Triangle" (Nantes), "La métairie" (La Roche S / Yon) And "La Rose des Vents" (St Nazaire), the SMPR in Nantes and the Addictions Network of the Nantes Region (RTRN)

Funding

Funding status	Public
Details	Interministerial Mission for Combating Drugs and Addictive Behaviours (MILDECA)

Governance of the database

Sponsor(s) or organisation(s) responsible	Chu de Nantes
Organisation status	Public
Presence of scientific or steering committees	No

Additional contact

Main features

Type of database

Type of database	Study databases
Study databases (details)	Not-repeated cross-sectional studies (except case control studies)
Database recruitment is carried out by an intermediary	A selection of health institutions and services

Database recruitment is is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	The study will focus on patients with a prescribed OST due to opioid dependence, whether the OST is methadone, buprenorphine (+/- naloxone) or a morphine-based drug. Recruitment is multicentric (10 centres in the western region participated in this study)

Database objective

Main objective	assess the current prevalence of addictive comorbidities in opioid-dependent subjects who have been receiving opioid substitution therapy (OST) for at least 6 months.
Inclusion criteria	Adult Treatment with methadone or buprenorphine (+/- naloxone) or morphine as a substitute, prescribed for opioid dependence OST established for at least 6 months Incarceration of less than one month if monitored by a Regional Medical and Psychological Service (SMPR) in prison Good understanding of French, knowing how to read and write it.

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
Pathology	V - Mental and behavioural disorders
Gender	Male Woman
Geography area	National
Detail of the geography area	Nantes, Brest, Morlaix, Angers, Rennes, St Nazaire

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	11/2013
Date of last collection (YYYY or MM/YYYY)	2016
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	263
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire Face to face interview
Presence of a biobank	Yes
Contents of biobank	Whole blood
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	collection of data in consultation by the physician and/or nurse
Quality procedure(s) used	Verification of data by a Clinical Study Technician and the consistency of data by the data cell when entering it into the computer database
Participant monitoring	No
Followed pathology	
Links to administrative sources	No
Promotion and access	
Promotion	

Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only