

Méthaville ANRS (Agency for Research on AIDS and Viral Hepatitis) - Cohort of Opioid-Dependent Subjects Starting Methadone Treatment

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Last update : 06/29/2016 | Version : 1 | ID : 73307

General	
Identification	
Detailed name	Cohort of Opioid-Dependent Subjects Starting Methadone Treatment
Sign or acronym	Méthaville ANRS (Agency for Research on AIDS and Viral Hepatitis)
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ANSM 2008- A0277-48. Eudract number 2008-001338-28, ClinicalTrials.gov identifier: NCT00657397 and International Standard Randomised Controlled Trial Number Register ISRCTN31125511.
General Aspects	
Medical area	General practice
Pathology (details)	Opioid addiction
Health determinants	Addictions Medicine
Keywords	methadone, opioids, buprenorphine, cannabis and other illicit substances, treatment, addiction
Scientific investigator(s) (Contact)	
Name of the director	Carrieri
Surname	Patrizia
Email	pmcarrieri@aol.com
Unit	Communicable diseases; healthcare systems; companies (ESSEM)
Organization	SESSTIM
Name of the director	Morel

Surname	Alain
Address	Oppelia
Collaborations	
Funding	
Funding status	Public
Details	ANRS, Ministry of Health
Governance of the database	
Sponsor(s) or organisation(s) responsible	INSERM ANRS
Organisation status	Public
Presence of scientific or steering committees	Yes
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 care professionals A selection of health institutions and services
Database recruitment is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	Yes
Details	Performed at individual level
Additional information regarding sample selection.	221 opioid/opiate users wishing to enter a methadone programme were randomly divided into two groups: 155 began methadone treatment with a private general practitioner and 66 were treated in a specialised centre.
Database objective	

Main objective	To compare the non-inferiority of daily opioid use after one year of treatment (trial phase) in opiate-dependent patients that began methadone treatment through two different arms: private care versus specialised centres for substance dependence (CSAPA). After stabilising the prescribed methadone dose, patients may select the treatment location from the centres and investigators included in the study (2 initial arms may result in 4 possible groups). Secondary aims involve comparing the prevalence of HCV risk behaviours and treatment effectiveness among the groups during a 3-year follow-up in terms of: treatment adherence; prevalence of addictive behaviours; improvement in social insertion and quality of life; prevalence of psychiatric comorbidities; reduction in criminal acts; treatment satisfaction and cost effectiveness.
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Inclusion criteria	Opioid/opiate users wishing to enter a methadone programme.
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Population type

Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years)
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Population covered	Sick population
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Gender	Male Woman
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Geography area	National
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Detail of the geography area	France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2009
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Date of last collection (YYYY or MM/YYYY)	2012
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Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of	221
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individuals	
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	Health episodes; withdrawal symptoms; depressive episodes and suicide risk; pain
Declarative data (detail)	Paper self-questionnaire Face to face interview Phone interview
Details of collected declarative data	Sex; age; cannabis and drug use; history of drug use. Social factors: secondary school graduation certificate; children; living with partner; employment; housing; requiring food aid and history of incarceration.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception Others
Care consumption (detail)	Medicines consumption
Quality of life/perceived health (detail)	SF12, symptoms experienced.
Other (detail)	Psychoactive substance use; alcohol; criminal acts; doctor-patient relationship; psychiatric comorbidities and infections
Procedures	
Data collection method	By participating physicians (private and CSAPA)
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the participant (mail, e-mail, telephone etc.) Monitoring by contact with the referring doctor
Details on monitoring of participants	1-month follow-up with visits at 3, 6 and 12 months

Links to administrative sources	No
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Promotion and access

Promotion

Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=%28Methadone+Maintenance+Treatment+AND+opioid-dependent+AND++Carrieri+MP+[Author]%29+OR+M%C3%A9thaville
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Link to the document	methaville.docx
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Access

Terms of data access (charter for data provision, format of data, availability delay)	No access.
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Access to aggregated data	Access not yet planned
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Access to individual data	No access
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