NarcoFluVF - Case-Control Study on Narcolepsy Risk Factors Following Exposure to Anti-H1N1 Vaccines

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General

Identification

Detailed name	Case-Control Study on Narcolepsy Risk Factors Following Exposure to Anti-H1N1 Vaccines
Sign or acronym	NarcoFluVF
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CNIL No. 911190; CPP: DC2011/18 (23/02/11)

General Aspects

Medical area	Infectious diseases Neurology
Pathology (details)	Narcolepsy
Health determinants	Iatrogenic
Keywords	narcolepsy, H1N1, influenza, vaccines, exposure

Scientific investigator(s) (Contact)

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Collaborations

Participation in projects, networks and consortia	Yes
Details	VAESCO European Project

Funding

Funding status	Public
Details	ANSM, ECDC

Governance of the database

Sponsor(s) or organisation(s) responsible	Inserm
Organisation status	Public
Sponsor(s) or organisation(s) responsible	Bordeaux University
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)	Case control study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is is made on the basis of:	Another treatment or procedure

Database recruitment is carried out as part of an interventional study	No

Database objective

Main objective	The main aim of the study was to determine the risk factors for narcolepsy; particularly focussing on the potential impact of influenza, H1N1 infection and vaccination (especially against the H1N1 influenza pandemic). As such, the study was able to contribute to the European study coordinated by the VAESCO consortium and received funding from the ECDC. The secondary aim was to compare the characteristics of exposed and unexposed cases. The potential impact of genetic susceptibility is not outlined in the final report (depending on the analyses that will potentially be carried out on stored samples).
Inclusion criteria	Cases were defined as patients diagnosed with narcolepsy; validated and classed according to the Brighton Classification Criteria by an approval committee; with an index date between 01/04/2009 and 30/04/2011, and where the onset of excessive daytime sleepiness (EDS) occurred before 31/12/2004. Controls: Patients of the same age, sex and treated at the same centre as the case subject. Treatment unrelated to narcolepsy or anti-H1N1 vaccination.

Population type

Age	Childhood (6 to 13 years) Adolescence (13 to 18 years) Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Gender	Male Woman
Geography area	National

Detail of the geography area	14 centres across France.
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2011
Date of last collection (YYYY or MM/YYYY)	2012
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	Case: 85; Controls: 202
Data	
Database activity	Data collection completed
Type of data collected	Declarative data Biological data Administrative data
Declarative data (detail)	Face to face interview
Details of collected declarative data	Epworth Sleepiness Scale; demographic characteristics; medical history; immunisation history; viral and bacterial infection; treatment)
Biological data (detail)	Blood sample (HLA-DQB1 typing, genetic and antibody analyses).
Administrative data (detail)	Medical record
Presence of a biobank	Yes
Contents of biobank	Whole blood Serum Plasma
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	Face-to-face questionnaire for cases and by phone for cases and controls.

Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=narcoflu
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Research may be included in scientific papers and publications following the express approval of the AFSSAPS.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only