

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

Head :Pariente Antoine, Pharmacoepidemiology

Dauvilliers Yves, National Reference Centre for Narcolepsy/Sleep Laboratory

Last update : 07/05/2016 | Version : 1 | ID : 73060

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)

Name of the director Pariente

Surname Antoine

Phone +33 (0)5 57 57 46 75

Email antoine.pariente@u-bordeaux2.fr

Unit Pharmacoepidemiology

Organization Inserm, Bordeaux University Hospital

Name of the director Dauvilliers

Surname Yves

Phone	+33 (0)4 67 33 74 78
Email	y-dauvilliers@chu-montpellier.fr
Unit	National Reference Centre for Narcolepsy/Sleep Laboratory
Organization	Montpellier University Hospital

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 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
---------------------------	---------------------------------