PIUS - Patient reported Instanyl® Use Study

Head :Moore Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Blin Patrick, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

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General

Identification

Detailed name	Patient reported Instanyl® Use Study
Sign or acronym	PIUS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS 11.168, CNIL 911153

General Aspects

Medical area	Cancer research
Health determinants	Addictions Medicine
Keywords	opioid, breakthrough pain, misuse, abuse, risk management plan, Instanyl®, fentanyl, cancer, Pharmacoepidemiology, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

Name of the director	Moore
Surname	Nicholas
Address	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33 (0)5 57 57 46 75
Email	nicholas.moore@pharmaco.u-bordeaux2.fr
Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux

Name of the director	Blin
Surname	Patrick
Address	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX Cedex
Phone	+ 33 (0)5 57 57 46 75
Email	patrick.blin@pharmaco.u-bordeaux2.fr
Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organization	Université Bordeaux

Collaborations

Funding

Funding status	Private
Details	Nycomed (unconditional support)

Governance of the database

Sponsor(s) or organisation(s) responsible	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
Organisation status	Public

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 care professionals
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 is conducted among patients who received a dispensation of Instanyl® in a non-hospital pharmacy. These pharmacies are identified by the wholesaler who distributes the drug along with study information sheet (pharmacist and patient) and study questionnaire.

Database objective

Main objective	The objective is to evaluate the misuse, diversion and abuse of Instanyl® reported by patients in real life. Data collected in the study on off-label prescriptions will complement the study data in five north-European countries (LINUS study, record Linkage Instanyl Use Study).
Inclusion criteria	Patient who received a dispensation of Instanyl® from non-hospital pharmacies

Population type

Age	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	Non-hospital pharmacies in metropolitan 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)	[500-1000[individuals
Details of the number of individuals	600 patients inclus - 600 patients included

Data	
Database activity	Data collection completed
Type of data collected	Declarative data
Declarative data (detail)	Paper self-questionnaire
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	Patients agreeing to participate completed a strictly anonymous questionnaire.
Participant monitoring	No
Links to administrative sources	No
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	A confidential study report was delivered to the pharmaceutical company. Ownership of study data is the subject of an agreement between the University of Bordeaux Segalen and the pharmaceutical company. Terms for third-party access to the database are to be defined.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only