

PIUS - Patient reported Instanyl® Use Study

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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

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Organization	Université Bordeaux

Collaborations

Funding

Funding status	Private
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Details	Nycomed (unconditional support)
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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 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.
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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).
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Inclusion criteria	Patient who received a dispensation of Instanyl® from non-hospital pharmacies
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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)
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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	Non-hospital pharmacies in metropolitan France
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Data collection

Dates

Date of first collection (YYYY or MM/YYYY)	2011
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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)	[500-1000[individuals
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Details of the number of individuals	600 patients inclus - 600 patients included
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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