CADEUS - Cox-2 and tNSAIDs: Description of users

Head :MOORE Nicholas, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
FOURRIER-REGLAT Annie, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen
BLIN Patrick, Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Last update : 06/25/2012 | Version : 1 | ID : 2926

General

Identification

Detailed name	Cox-2 and tNSAIDs: Description of users
Sign or acronym	CADEUS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTI-RS 03.135, CNIL 903102

General Aspects

Medical area	General practice Rheumatology
Health determinants	Iatrogenic
Others (details)	Use of Cox-2 and traditional NSAIDs
Keywords	Celebrex, NSAIDs, traditional non-steroidal anti-inflammatory drugs, gastroprotective drugs, cardiovascular events, gastrointestinal events, health authotities (Comité Economique des Produits de Santé), Cyclo-oxygenase 2, coxibs, Vioxx, use, pharmacoepidemiology, cohort, 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	05 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	FOURRIER-REGLAT
Surname	Annie
Address	Bât du Tondu - Case 41 - 146, Rue Léo Saignat - 33076 BORDEAUX cedex
Phone	05 57 57 46 75
Email	annie.fourrier@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	05 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	Mixed
Details	Laboratoire Merck Sharp et laboratoire Pfizer (soutiens inconditionnels) - Merck Sharp and Pfizer (unconditional support)

Governance of the database

Sponsor(s) or organisation(s)	INSERM

responsible	
Organisation status	Public

Additional contact

Main features

Type of database

Additional information regarding sample selection.	Patients who received between August 2003 and June 2004 dispensation of a coxib or tNSAID were randomly selected from the CNAM-TS database using the following criteria: not dead according to information in the ERASME database, living in metropolitan France with a valid address; having had a dispensation of an NSAID of interest during the month preceding selection; with at least one healthcare reimbursement within six months preceding the date of dispensation; for whom the contact details of the prescribing physician were available,; not previously selected from the source population; not being listed as a subject under guardianship or in prison.

Database objective

Main objective	The objective of this study was to better understand the use of anti-inflammatory drugs, cyclo-oxygenase 2 (COX-2) or coxib (Vioxx®, Celebrex®) and traditional anti-inflammatory drugs (tNSAIDs, e.g. Aspirin, Ibuprofen) in France and to describe and assess the risks of adverse events possibly related to treatment.
Inclusion criteria	Patient randomly selected from the source population using the following criteria: not dead according to the ERASME database, living in France with a valid address, with dispensation of an NSAIDs of interest during the month preceding selection, with at least one healthcare reimbursement within six months preceding the date of dispensation, for whom the contact details of the prescribing physician were available, not previously selected from the source population, not being listed under guardianship or in prison; patient agreeing to participate in the study

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	Metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2003
Date of last collection (YYYY or MM/YYYY)	2005
Size of the database	
Size of the database (number of individuals)	Greater than 20 000 individuals
Details of the number of individuals	45 217 patients inclus - 45 217 patients included
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Declarative data Administrative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Paper self-questionnaire
Administrative data (detail)	Name, address and telephone number of the patient, the prescribing physician, the general practitioner.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality Health care consumption and services

Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	A self-administered questionnaire sent to each selected patient and prescriber of the NSAID of interest, has allowed the collection of the information requested by Comité Economique des Produits de Santé. For patients agreeing to participate in the study, healthcare reimbursement data for six months before and six months after the reference date (dispensation date of NSAID of interest) were retrieved from the CNAM-TS database. Hospitalizations for cardiovascular events or digestive having occurred between the reference date and the date of questionnaire completion have been documented (retrieval of hospital discharge summaries by a CRA from the prescribing physician or general practitioner with return to the Department of Pharmacology by post). The reason for hospitalization was subsequently validated by a committee blinded to the NSAID of interest and according to predefined diagnostic criteria.
Participant monitoring	No
Links to administrative sources	Yes
Linked administrative sources (detail)	Extraction from the ERASME database of the CNAM-TS
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed?term
Access	
Terms of data access (charter for data provision, format of data, availability delay)	The confidential study reports were submitted to the pharmaceutical companies. The study reports and scientific communications (posters, articles, ...) are validated by the study Scientific Committee. Ownership of study data was the subject of an agreement between the University Bordeaux Segalen and pharmaceutical companies. 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