EMES - Pragmatic pharmacoeconomic assessment of Sinovial® in the treatment of gonarthrosis

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General

Identification

Detailed name	Pragmatic pharmacoeconomic assessment of Sinovial® in the treatment of gonarthrosis
Sign or acronym	EMES
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	CCTIRS 03.457, CNIL 903389

General Aspects

Medical area	Rheumatology
Health determinants	Iatrogenic
Others (details)	Gonarthrosis
Keywords	hyaluronic acid viscosupplementation, gonarthrosis, safety, Sinovial®, cost, effectiveness, pharmacoepidemiology, cohort, Department of Pharmacology, Bordeaux

Scientific investigator(s) (Contact)

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Unit	Service de Pharmacologie, CIC-P 0005-INSERM U657- Université Bordeaux Segalen

Organization	Université Bordeaux
Collaborations	
Funding	
Funding status	Mixed
Details	Laboratoire Genévrier
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)	Longitudinal study (except cohorts)
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.	Sample of subjects that have had an injection of Sinovial®. Subjects were identified by rheumatologists and by functional rehabilitation physicians prescribing Sinovial ® (list provided by Laboratories GENEVRIER).
Database objective	
Main objective	The objective was to compare the cost of two therapeutic strategies: Sinovial® and other care versus other care alone.
Inclusion criteria	Patient agreed to participate in this study and having signed the consent form; Patient having had a first injection of Sinovial® between 01/01/2003

	and 31/03/2003; Patient having never previously received viscosupplementation treatment; Patient aged 20 years and over; Patient affiliated to the general health insurance system for at least 12 months at the time of first injection
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	Rheumatologists and functional rehabilitation physicians in metropolitan France
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2004
Date of last collection (YYYY or MM/YYYY)	2005
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	408
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)	Patient name, first name, date of birth, social security number
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Data collection was conducted through two questionnaires (one for the physician and the other for the patient). Further information about care consumed by each patient were also retrieved from the database ERASME (Extraction, Recherche, Analyse pour le Suivi Médico-Economique) database of the CNAM-TS (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés).
Participant monitoring	Yes
Links to administrative sources	Yes
Linked administrative sources (detail)	ERASME database (Extraction, Recherche, Analyse pour le Suivi Médico-Economique) of the CNAM-TS (Caisse Nationale d'Assurance Maladie des Travailleurs Salariés)
Promotion and access	
Promotion	
Access	
Terms of data access (charter for data provision, format of data, availability delay)	A study report was delivered to the pharmaceutical company after validation by the study Scientific Committee. Scientific articles are currently being drafted. 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