

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

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Last update : 09/05/2017 | Version : 1 | ID : 2959

## 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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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 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)
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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	Rheumatologists and functional rehabilitation physicians in metropolitan France
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## Data collection

### Dates

Date of first collection (YYYY or MM/YYYY)	2004
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Date of last collection (YYYY or MM/YYYY)	2005
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### Size of the database

Size of the database (number of individuals)	< 500 individuals
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Details of the number of individuals	408
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### Data

Database activity	Data collection completed
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Type of data collected	Clinical data Declarative data Administrative data
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Clinical data (detail)	Direct physical measures
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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
<b>Procedures</b>	
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)
<b>Promotion and access</b>	
<b>Promotion</b>	
<b>Access</b>	
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