

PASS-ARTHROSE - Patient Acceptable Symptomatic State

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General

Identification

Detailed name	Patient Acceptable Symptomatic State
Sign or acronym	PASS-ARTHROSE
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	Numéro CNIL 909039, Numéro CPP = NA, Afssaps = NA

General Aspects

Medical area	General practice Rheumatology
Others (details)	Arthrosis of the lower limbs
Keywords	evaluation of the pain and response to analgic treatment, PASS, Minimal Clinically Important Improvement (MCII)

Scientific investigator(s) (Contact)

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Unit	Sanofi Aventis

Collaborations

Funding

Funding status	Private
Details	Sanofi-aventis France

Governance of the database

Sponsor(s) or organisation(s) responsible Sanofi-aventis France

Organisation status Private

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
An administrative base or a register

Database recruitment is carried out as part of an interventional study No

Database objective

Main objective Determine, in patients suffering from arthrosis of the lower limbs, the percentage of patients that find their pain "acceptable" at rest and when movement, after one week of treatment, according to the PASS concept (Patient Acceptable Symptomatic State).

Inclusion criteria Patients must:
? be ambulatory,
? be aged 50 years or older,
? consult for a defined gonarthrosis and/or coxarthrosis according to the clinical or radiological criteria of the American College of Rheumatology,
? be symptomatic with pain greater or equal to 3 on a numerical pain scale from 0 to 10, at rest or during movement, in the 24 hours preceding entry in the study,
? requiring the taking of an antalgic treatment for a duration of at least one week,
? be able and accept to complete a self-evaluation questionnaire,
? accepting to participate in the survey.

Population type

Age 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 French territory (France+overseas possessions)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 2009

Date of last collection (YYYY or MM/YYYY) 2010

Size of the database

Size of the database (number of individuals) [1000-10 000[individuals

Details of the number of individuals 3329

Data

Database activity Data collection completed

Type of data collected Clinical data
Declarative data
Administrative data

Clinical data (detail) Medical registration

Declarative data (detail) Paper self-questionnaire

Administrative data (detail) ? age, sex, ? weight, height, ? social and occupational category (INSEE classification),

Presence of a biobank No

Health parameters studied Health care consumption and services
Quality of life/health perception

Care consumption (detail) Medicines consumption

Procedures

Data collection method	general practice, evaluation of the pain and response to antalgic treatment, arthrosis of the lower limbs Doctor's questionnaire patient self-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)	methods for accessing the database are currently being defined SFR 2010 poster. Publication scheduled in 2011.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only