

3A-Pégase - Programme d'études 3A-Pégase (Pharmaco-Epidémiologie de la Gonarthrose et de la coxArthoSE)

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General

Identification

Detailed name Programme d'études 3A-Pégase (Pharmaco-Epidémiologie de la Gonarthrose et de la coxArthoSE)

Sign or acronym 3A-Pégase

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation N°CNIL : 909473

General Aspects

Medical area Rheumatology

Others (details) Gonarthrosis, coxarthrosis

Keywords Symptomatic slow-acting anti-arthritics, intake of NSAIDs

Scientific investigator(s) (Contact)

Name of the director Grimaldi - Bensouda

Surname Lamiae

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Organization LA-SER

Collaborations

Funding

Funding status Private

Details	EXPANSCIENCE, Pierre FABRE, GENEVRIER, NEGMA, NOVARTIS, ROTTAPHARM
Governance of the database	
Sponsor(s) or organisation(s) responsible	LA-SER
Organisation status	Private
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 carried out as part of an interventional study	No
Additional information regarding sample selection.	Eligible patients are recruited by general practitioners or participating private-practice rheumatologists and exercising in metropolitan France
Database objective	
Main objective	Evaluate the impact (benefit and risk) of osteoarthritis treatments in terms of public health.
Inclusion criteria	Men or women, aged 18 years or older, having painful gonarthrosis and/or coxarthrosis, non-treated or treated with a symptomatic slow-acting anti-arthritic for less than 3 months.
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)	03/2010
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1900 patients
Data	
Database activity	Current data collection
Type of data collected	Clinical data Declarative data
Clinical data (detail)	Direct physical measures
Declarative data (detail)	Phone interview
Presence of a biobank	No
Health parameters studied	Health event/morbidity
Procedures	
Data collection method	The data is collected using medical questionnaires and during standardized telephone interviews with the patient included. The telephone interviews are conducted after sending an interview guide beforehand (visual support).
Participant monitoring	Yes
Details on monitoring of participants	Patients included are followed for 12 months. Follow-up for patients included comprises 4 telephone interviews: 1 month after inclusion, then at 4, 8 and 12 months of follow-up. After the 12 months of follow-up, a medical questionnaire is

completed by the participating practitioner.

Links to administrative sources	No
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Promotion and access

Promotion

Access

Terms of data access (charter for data provision, format of data, availability delay)	Methods for disseminating and access to the data are being finalized.
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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