

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

Head :Grimaldi - Bensouda Lamiae

Last update : 07/13/2012 | Version : 1 | ID : 2611

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

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| 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 |

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| 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.

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| Links to administrative sources | No |
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Promotion and access

Promotion

Access

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| 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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