

ESPOIR - Assessment and Follow-Up of Early Undifferentiated Rheumatoid Arthritis

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General

Identification

Detailed name Assessment and Follow-Up of Early Undifferentiated Rheumatoid Arthritis

Sign or acronym ESPOIR

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation CNIL: 902156 (02-1387); Afssaps: DGS 2002/0541; n°CPP: 02 03 07 (12/07/2002)

General Aspects

Medical area Rheumatology

Health determinants Addictions
Genetic
Occupation
Social and psychosocial factors

Keywords rheumatoid arthritis, Cohort

Scientific investigator(s) (Contact)

Name of the director Combe

Surname Bernard

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Organization Société Française de Rhumatologie

Collaborations

Funding

Funding status	Mixed
Details	Société Française de Rhumatologie - Institut National de la Santé et de la Recherche Médicale- Laboratoire MSD- Laboratoire Pfizer- Laboratoire Abbvie- Laboratoire Roche Chugai
Governance of the database	
Sponsor(s) or organisation(s) responsible	Société Française de Rhumatologie
Organisation status	Public
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Additional information regarding sample selection.	Multi-centric from pre-inclusion criteria.
Database objective	
Main objective	To form a multicentric French cohort for early arthritis (less than 6 months duration) in order to establish a database for diagnostic, prognostic, medico-economic and pathogenetic studies.
Inclusion criteria	- Men or women - between 18 and 70 years old - affiliated with a social security scheme - who have at least 2 forms of arthritis for less than 6 weeks/months - who have not received any corticosteroids within the last 6 months (except for treatments lasting less than 2 weeks and infiltration if over 4 weeks before inclusion; except for oral steroid therapy over a period less than 2 weeks, averaging less than 20mg/day, concluded at least 15 days prior to inclusion)

Population type

Age
Adulthood (19 to 24 years)
Adulthood (25 to 44 years)
Adulthood (45 to 64 years)
Elderly (65 to 79 years)

Population covered
Sick population

Gender
Male
Woman

Geography area
National

Detail of the geography area
France CHU Nord (Amiens), CHU Pellegrin Tripode (Bordeaux), CHU La Cavale Blanche (Brest), CHU R.Salengro (Lille), CHU Lapeyronie (Montpellier), CHU St Antoine (Paris), CHU Avicenne (Paris), CHU La Pitié Salpêtrière (Paris), CHU Cochin (Paris), CHU Bicêtre (Paris), CHU Bichat-Lariboisière (Paris), CHU Bois Guillaume (Rouen), CHU Hautepierre (Strasbourg), CHU Trousseau (Tours)

Data collection

Dates

Date of first collection (YYYY or MM/YYYY)
10/2002

Size of the database

Size of the database (number of individuals)
[500-1000[individuals

Details of the number of individuals
813

Data

Database activity
Current data collection

Type of data collected
Clinical data
Declarative data
Paraclinical data
Biological data
Administrative data

Clinical data (detail)
Medical registration

Declarative data (detail)
Paper self-questionnaire
Face to face interview
Phone interview

Paraclinical data (detail)	- frontal hand and wrist x-rays, frontal and three quarter feet x-rays - feet and hand ultrasounds - hand and feet MRI (only in certain centres)
Biological data (detail)	DNA (tissue and synovial fluid), serums, usual biological samples: blood count, platelets, erythrocyte sedimentation rate, C-reactive protein, aspartate aminotransferase, alanine aminotransferase, gamma GT (baseline), glucose, rheumatoid factor, anti-cyclic citrullinated peptide, antinuclear antibodies (baseline), anti-native DNA (baseline), human leukocyte antigens (baseline) alkaline phosphatase (baseline), creatine (baseline)
Administrative data (detail)	Gender, date of birth, place of birth, ethnic origin, level of education
Presence of a biobank	Yes
Contents of biobank	Serum Fluids (saliva, urine, amniotic fluid, ?) Tissues DNA
Details of biobank content	Serum bank, other fluids, tissue, DNA bank
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Hospitalization Medical/paramedical consultation Medicines consumption
Procedures	
Data collection method	Data gathered by CRF and recorded on Access database. Data sent weekly to coordinating centre.
Participant monitoring	Yes
Details on monitoring of participants	Total follow-up duration: 10 years (current request for 10 additional years for a total duration of 20 years in progress). Follow-up every 6 months for 2 years and then becoming annual. Self-administered questionnaire, medical examination and normal biological samples are carried out at each visit. X-rays are carried out at baseline, 6 months, 12 months, 18 months, 2 years, 3 years, 5 years and 10 years. Biobank (serum) is carried out at baseline, 6 months, 12 months, 18 months, 2 years, 3 years, 5 years and 10 years. Urine is collected at baseline

until 2 years. An overview of patients who were not followed-up (lost to follow-up, refusal) is carried out twice a year.

Links to administrative sources No

Promotion and access

Promotion

Link to the document http://sfr.larhumatologie.fr/rc/rhumatologie/htm/Article/2010/59d645a5cc26d0e80d4052f3ca0a70ab/src/htm_fullText/fr/Combe%20ESPOIR%20bonsoi_JBS%20271911.pdf

Link to the document http://sfr.larhumatologie.fr/rc/rhumatologie/htm/Article/2010/59d645a5cc26d0e80d4052f3ca0a70ab/src/htm_fullText/fr/Fautrel%20Rheumatology%202009%2009-0579.pdf

Link to the document http://sfr.larhumatologie.fr/rc/rhumatologie/htm/Article/2010/59d645a5cc26d0e80d4052f3ca0a70ab/src/htm_fullText/fr/090201-Echo%20ESPOIR.pdf

Link to the document http://sfr.larhumatologie.fr/rc/rhumatologie/htm/Article/2010/59d645a5cc26d0e80d4052f3ca0a70ab/src/htm_fullText/fr/Lukas%20ESPOIR%20ClinExpRheum%202009.pdf

Link to the document http://sfr.larhumatologie.fr/rc/rhumatologie/htm/Article/2010/59d645a5cc26d0e80d4052f3ca0a70ab/src/htm_fullText/fr/Benhamou%20J%20rheumatol%20JR%202009.pdf

Link to the document http://sfr.larhumatologie.fr/rc/rhumatologie/htm/Article/2010/59d645a5cc26d0e80d4052f3ca0a70ab/src/htm_fullText/fr/Guennoc-JRheumatol%20june%2009.pdf

Link to the document <http://tinyurl.com/HAL-ESPOIR>

Description List of publications in HAL

Link to the document <http://www.ncbi.nlm.nih.gov/pubmed/?term=espoir+AND+arthritis>

Description List of publications in Pubmed

Access

Terms of data access (charter for data provision, format of data, availability delay) Project data following call for proposals (twice per year) addressed to the Chairman of the Scientific Council and reviewed by two specialists. Final

approval is given by the Scientific Council. Specific data are transferred after signing an agreement. A list of publications and works is available on the website.

Access to aggregated data

Access on specific project only

Access to individual data

Access on specific project only