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)

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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 Salpétrière (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