DUO - Descriptive epidemiological study of therapeutic decision-making during management of rheumatoid arthritis: physicians' criteria and patients' opinions

Head :Roche Medical Data Center

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General

Identification

Detailed name	Descriptive epidemiological study of therapeutic decision-making during management of rheumatoid arthritis: physicians' criteria and patients' opinions
Sign or acronym	DUO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22021

General Aspects

Medical area	Rheumatology
Study in connection with Covid-19	No
Pathology (details)	Rheumatoid arthritis
Health determinants	Iatrogenic Medicine
Keywords	Tocilizumab

Scientific investigator(s) (Contact)

Name of the director	Roche Medical Data Center
Address	4 cours de l'Ile Seguin - 92650 BOULOGNE-BILLANCOURT
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations

Participation in projects, networks and consortia	No

Funding

Funding status	Private

Governance of the database

Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes

Additional contact

Name of the contact	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html

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 is made on the basis of:	Medication(s) taken
Database recruitment is carried out as part of an interventional study	No

Database objective

Main objective	Primary objectives: To describe the criteria used for therapeutic decision-making for RA patients: - clinical, biological and radiological data, impact of RA on patients' life according to physicians; - impact of RA on patients' life according to patients; - physicians' characteristics. Secondary objectives: - To describe the characteristics of the included patient population depending on treatment

	modifications after the inclusion visit.
Inclusion criteria	Inclusion criteria: - Adult (aged >= 18 years); - Treated for RA; - Willing and able to complete the self-questionnaire in French on the impact of RA during the visit; - Having been informed about the study orally and in writing and not objecting to their data being processed. Exclusion criteria: - Patients participating in another clinical study assessing RA treatment at the time of inclusion.
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
Pathology	M05-M14 - Inflammatory polyarthropathies
Gender	Male Woman
Geography area	National
Data collection	
Dates	
Date of first collection (YYYY or MM/YYYY)	2009
Date of last collection (YYYY or MM/YYYY)	2009
Size of the database	
Size of the database (number of individuals)	[1000-10 000[individuals
Details of the number of individuals	1115
Data	

Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Date of inclusion visit - Patient information about the study - General data: age, sex, weight, height - Date of initial diagnosis - Disease characteristics - Ongoing symptomatic treatment or corticosteroids (dose) - Past and current DMARDs: names of compounds (methotrexate, hydroxychloroquine, sulfasalazine, gold salts, leflunomide, D-penicillamine, azathioprine, cyclosporine, infliximab, etanercept, adalimumab, abatacept, rituximab, anakinra, others), ongoing therapeutic regimens, route of administration and date of implementation of methotrexate (if applicable), date of last infusion of rituximab (if applicable) - Safety: any adverse reactions or discomfort experienced by the patient, according to the physician - Patient interview: global RA activity (VAS), degree of asthenia, intensity of pain, duration of morning stiffness, nocturnal wakening related to RA - Clinical examination: localisation of tender joints and swollen joints (out of 28) - Biological examination (last available for 2009): dates and values of ESR (1st hour), CRP and hemoglobin concentration - DAS 28 (if calculated), with ESR or CRP for the calculation - Treatment prescribed at the end of the visit (whether treament modified or not) - Conditions under which the patient self-questionnaire was completed: before the visit/during the visit but before the therapeutic decision was made, other (to precise).
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services Quality of life/health perception
Care consumption (detail)	Medicines consumption
Procedures	
Data collection method	paper
Classifications used	CDISC
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes

Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No

Promotion and access

Promotion

Access

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Presence of document that lists variables and coding procedures	Yes
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only