SPARE-1 - Description in real life of glucocorticoid-sparing in patients treated with Roactemra® for moderate to severe rheumatoid arthritis

Head :Roche Medical Data Center

Last update : 08/23/2022 | Version : 1 | ID : 74129

General

Identification

Detailed name	Description in real life of glucocorticoid-sparing in patients treated with Roactemra® for moderate to severe rheumatoid arthritis
Sign or acronym	SPARE-1
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML25634

General Aspects

Medical area	Rheumatology
Study in connection with Covid-19	No
Pathology (details)	Moderate to severe rheumatoid arthritis
Health determinants	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,	No

networks and consortia

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 objective : To describe in real life the glucocorticoid-sparing effect after 12 months of treatment with RoActemra® in patients with moderate to severe RA and to determine predictive factors. Secondary objectives: 1. to describe the characteristics of the population at baseline; 2. to evaluate efficacy of RoActemra® (EULAR response and/or glucocorticoid dosage) in real life;

	3. to describe therapeutic management of RA [glucocorticoids and/or conventional Disease-Modifying Anti-Rheumatic Drug(s) (DMARDs) in combination with RoActemra®]; 4. to describe change in functional capacity of patients and impact of the disease on the patient over time during follow-up (HAQ-DI and RAID self-report questionnaires); 5. to assess safety of RoActemra®.
Inclusion criteria	Inclusion criteria: - Patients aged 18 years and older; - Patients with moderate to severe rheumatoid arthritis; - Patients for whom the rheumatologist decided to initiate treatment with RoActemra®; - Patients taking oral glucocorticoids >5 mg/day of prednisone or equivalent for at least 3 months; - Patients having received oral and written information about the study and having raised no objections to the collection and computer processing of his/her personal data. Exclusion criteria: - Patients participating in a clinical trial on rheumatoid arthritis at time of inclusion could not participate to the study.
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)	2011
Date of last collection (YYYY or	2013

MM/YYYY)	
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	321
Data	
Database activity	Data collection completed
Type of data collected	Clinical data Biological data
Clinical data (detail)	Medical registration
Details of collected clinical data	Validation of inclusion and exclusion criteria - Sociodemographic data - Medical history and concomitant diseases - RA history, previous and/or ongoing RA treatments - Most recent clinical and biological data - Physician global assessment of RA activity (asymptomatic to very severe) - RA treatments and reason for discontinuation where applicable - Treatment with RoActemra® - Adverse events - Reason for early study discontinuation - HAQ-DI, RAID scale.
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health event/mortality 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