PEPS - PharmacoEpidemiological study of the imPact of RoActemra® treatment on fatigue in rheumatoid arthritis patientS in a real life setting

Head :Roche Medical Data Center

Last update : 08/23/2022 | Version : 1 | ID : 74130

General

Identification

Detailed name	PharmacoEpidemiological study of the imPact of RoActemra® treatment on fatigue in rheumatoid arthritis patientS in a real life setting
Sign or acronym	PEPS
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML22457

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 objective: To describe in a real life setting the evolution of fatigue in patients with moderate to severe RA during the first 4 months of RoActemra® treatment, as well as to search for predictive factors of an improvement in this symptom. Secondary objectives: - To describe patient baseline characteristics and level of fatigue experienced at inclusion by the

	patient population treated with RoActemra®; - To evaluate the correlation between the evolutions of fatigue as assessed by FACIT-Fatigue questionnaire and VAS fatigue during the first 4 months of RoActemra® treatment; - To evaluate the time of onset of RoActemra® effect on fatigue in a real life setting; - To assess the correlation between evolution of fatigue and disease activity during 4 months of RoActemra® treatment; - To evaluate the PASS of the fatigue scales (FACIT-Fatigue, VAS fatigue, SF36 vitality) after 4 months of RoActemra® treatment; - To evaluate the correlation between evolution of fatigue and other patient reported outcomes (PROs): pain, quality of sleep, disability, SF36 vitality, anxiety, depression; - To describe the management of RA patients treated with RoActemra®; - To describe all adverse events occurring during the study.
Inclusion criteria	Inclusion criteria: - Male or woman aged over 18 years. - Patients presenting with moderate to severe rheumatoid arthritis and for which treatment with RoActemra(R) was planned by the investigator; - Patients willing and able to complete, during consultations and at home, the study questionnaires aimed at evaluating the impact of their disease and treatment; - Patients who received complete written and oral information about the study, and who gave their consent for future automated processing of the data generated during the study. Exclusion criteria: - Patient with known hypersensitivity to RoActemra®, or to any constituent of the study medication; - Patient presenting with an active concomitant infection; - Patient currently participating in a clinical trial aimed at evaluating another treatment in rheumatoid arthritis.
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)	2010
Date of last collection (YYYY or MM/YYYY)	2011

Size of the database

Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	721

Data

Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Patient demographic characteristics - History of rheumatoid arthritis - Concomitant treatments - Tender and swollen joint counts - Biological parameters - Management of rheumatoid arthritis - Adverse events - FACIT-Fatigue - VAS fatigue - VAS pain - VAS disease activity - VAS quality of sleep - HAQ-DI - SF36 vitality - HADS - PASS Fatigue.
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

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