ACTSOLO - Evaluation of factors influencing use of Roacterma® as monotherapy in Rheumatoid Arthritis patients in a real life setting

Head :Medical data center

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General

Identification

Detailed name	Evaluation of factors influencing use of Roacterma® as monotherapy in Rheumatoid Arthritis patients in a real life setting
Sign or acronym	ACTSOLO
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML27873

General Aspects

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

Scientific investigator(s) (Contact)

Name of the director	Medical data center
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	
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 factors influencing the use of RoActemra® as monotherapy or in combination with DMARDs in patients with rheumatoid arthritis Secondary objectives : - To describe the characteristics of patients treated with RoActemra® as monotherapy or in combination with another treatment. - To describe impact of physician characteristics on use of RoActemra® as monotherapy or in combination. - For patients on RoActemra® monotherapy, to describe reasons for discontinuation or non-use of csDMARDs. - To evaluate treatment maintenance one year after RoActemra® initiation in a real-life setting. - To describe efficacy of RoActemra® in real conditions of use.

	- To describe effect of RoActemra® on quality of life in real conditions of use. - To assess safety profile of RoActemra® in real conditions of use.
Inclusion criteria	Inclusion criteria : - Patient >=18 years of age - Patient with rheumatoid arthritis, for whom the rheumatologist decided to start RoActemra® in combination with a csDMARD or as monotherapy - Patient having received both oral and written information about the study, without any objections for the use of his/her personal data
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)	2013
Date of last collection (YYYY or MM/YYYY)	2014
Size of the database	
Size of the database (number of individuals)	[500-1000[individuals
Details of the number of individuals	603
Data	
Database activity	Data collection completed

Type of data collected	Clinical 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 ; Pain VAS, fatigue VAS, and patient's global assessment of disease activity ; HAQ-DI, RAID scale, and PASS.
Presence of a biobank	No
Procedures	
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
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only