

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

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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

Funding

Funding status	Private
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Governance of the database

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

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

Type of database

Type of database	Study databases
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Study databases (details)	Cohort study
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Database recruitment is carried out by an intermediary	A selection of health institutions and services
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Database recruitment is made on the basis of:	Medication(s) taken
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Database recruitment is carried out as part of an interventional study	No
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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;
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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 MM/YYYY)	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
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Presence of document that lists variables and coding procedures	Yes
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Access to aggregated data	Access on specific project only
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Access to individual data	Access on specific project only
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