

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

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| 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

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|-----------------------------------|---|
| 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)

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

Collaborations

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|----------------------------|----|
| Participation in projects, | No |
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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 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 |
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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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