# 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'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.<br><br>Secondary objectives:<br>1. to describe the characteristics of the population at baseline;<br>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®];<br>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);<br>5. to assess safety of RoActemra®. |
| Inclusion criteria | Inclusion criteria:<br>- Patients aged 18 years and older;<br>- Patients with moderate to severe rheumatoid arthritis;<br>- Patients for whom the rheumatologist decided to initiate treatment with RoActemra®;<br>- Patients taking oral glucocorticoids >5 mg/day of prednisone or equivalent for at least 3 months;<br>- 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.<br><br>Exclusion criteria:<br>- 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)<br>Adulthood (25 to 44 years)<br>Adulthood (45 to 64 years)<br>Elderly (65 to 79 years)<br>Great age (80 years and more) |
| Population covered | Sick population |
| Pathology | M05-M14 - Inflammatory polyarthropathies |
| Gender | Male<br>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<br>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<br>Health event/mortality<br>Health care consumption and services<br>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

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|---|---|
| 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 |