

TANDEM - Subcutaneous Tocilizumab in monotherapy or in combination with csDMARD in patients with moderate to severe active Rheumatoid Arthritis and followed by hospital and office-based rheumatologists: Non-interventional study to describe realworld drug retention rate of the biotherapy at 1 year

Head :Medical data center

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General

Identification

Detailed name Subcutaneous Tocilizumab in monotherapy or in combination with csDMARD in patients with moderate to severe active Rheumatoid Arthritis and followed by hospital and office-based rheumatologists: Non-interventional study to describe realworld drug retention rate of the biotherapy at 1 year

Sign or acronym TANDEM

CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation ML29256

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

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|---|-----------|
| 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 |
|---|-----|

Additional contact

Main features

Type of database

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|------------------|-----------------|
| 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 carried out as part of an interventional study | No |
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Database objective

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|----------------|--|
| Main objective | <p>Primary objective : To assess the drug retention rate of TCZ sc at 12 months under real-world conditions in patients with moderate to severe active RA followed by hospital- and office-based rheumatologists</p> <p>Secondary objectives :</p> <ul style="list-style-type: none">- To assess the drug retention rate of TCZ sc at 6 and 18 months.- To compare the drug retention of TCZ sc in monotherapy and in combination with MTX or other csDMARD.- To describe steroid dosing after introduction of TCZ sc with a stratification on the use of MTX or other csDMARDs at 6, 12 and 18 months.- To assess adherence to TCZ sc using a French |
|----------------|--|

version of the Compliance Questionnaire for Rheumatology 5 (CQR5) and patient diary at 6, 12 and 18 months.

- To evaluate the French version of the CQR5 by assessing the correlation with the data collected from the patient diary data.
- To describe the modalities of use of TCZ sc.
- To describe the management of RA and patients' healthcare pathway between hospital- and office-based rheumatologists.
- To describe the efficacy of TCZ sc under real-world conditions of use.
- To describe the characteristics of patients treated with TCZ sc and the characteristics of the involved physicians.
- To assess the tolerability profile of TCZ sc under real-world conditions of use.
- To describe the quality of life (QoL) in patients receiving TCZ sc under real-world conditions of use.

Inclusion criteria

Inclusion criteria :

- Patients at least 18 years-old.
- Patients with moderate to severe RA not previously treated with TCZ (iv or sc), for whom the rheumatologists have decided to initiate TCZ sc treatment as monotherapy or in combination with another csDMARD.
- Patients who have been informed verbally and in writing about this study, who do not object to their data being electronically processed or subjected to data quality control and who have signed the consent form.

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) | 2015 |
| Date of last collection (YYYY or MM/YYYY) | 2018 |
| Size of the database | |
| Size of the database (number of individuals) | < 500 individuals |
| Details of the number of individuals | 286 |
| Data | |
| Database activity | Data collection completed |
| Type of data collected | Clinical data |
| Clinical data (detail) | Medical registration |
| Details of collected clinical data | Eligibility /Consent form ; Inclusion criteria / Exclusion criteria ; Status ; Demography ; History of Rheumatoid Arthritis and Medical history ; Prior treatments ; Activity of RA : ESR / CRP ; Treatment with RoActemra® sc ; Hospitalization for RA ; Early termination ; Concomitant Treatment ; Adverse Events ; CQR-5/CQ5D/HAQDI. |
| Presence of a biobank | No |
| Procedures | |
| Data collection method | eCRF |
| 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 |
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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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