

REGATE - Longitudinal Study on Patients with Rheumatoid Arthritis and Study on Tolerance and Efficacy of Tocilizumab (REGistry-RoAcTEmra)

Head :Morel Jacques, Service de RhumatologieCHU Lapeyronie

Sibilia Jean, Service de rhumatologie, Centre national de références des maladies auto-immunes
systémiqueshôpital de Haute-pierreCHU de Strasbourg

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General

Identification

Detailed name Longitudinal Study on Patients with Rheumatoid Arthritis and Study on Tolerance and Efficacy of Tocilizumab (REGistry-RoAcTEmra)

Sign or acronym REGATE

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

General Aspects

Medical area Geriatrics
Rheumatology

Health determinants Medicine

Keywords RA, TCZ, tolerance, comorbidity, efficacy

Scientific investigator(s) (Contact)

Name of the director Morel

Surname Jacques

Address 191 Avenue du Doyen Gaston, Giraud, 34295
Montpellier, Cedex 5, France

Phone +33 (0)4 67 33 73 14

Email jacquesmorel@yahoo.com

Unit Service de RhumatologieCHU Lapeyronie

Organization CHU de

Name of the director	Sibilia
Surname	Jean
Address	avenue Molière, 67098 Strasbourg cedex, France.
Phone	+33 (0)3 88 12 79 54
Email	jean.sibilia@chru-strasbourg.fr
Unit	Service de rhumatologie, Centre national de références des maladies auto-immunes systémiqueshôpital de HautepierreCHU de Strasbourg
Organization	CHU de

Collaborations

Funding

Funding status Private

Details French Rheumatology Society

Governance of the database

Sponsor(s) or organisation(s) responsible Société Française de Rhumatologie

Organisation status Private

Sponsor(s) or organisation(s) responsible Club Rhumatiques et Inflammation

Organisation status Private

Additional contact

Main features

Type of database

Type of database Study databases

Study databases (details) Longitudinal study (except cohorts)

Database recruitment is carried out by an intermediary A selection of health institutions and services

Database recruitment is carried out as part of an interventional No

study

Database objective

Main objective The main objective of the REGATE study is to identify the tolerance and efficacy of Tocilizumab currently used for Rheumatoid Arthritis (RA).

Inclusion criteria - aged 18 or over
- patient with rheumatoid arthritis

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

Gender Male
Woman

Geography area National

Detail of the geography area France

Data collection

Dates

Date of first collection (YYYY or MM/YYYY) 01/2011

Date of last collection (YYYY or MM/YYYY) 10/2012

Size of the database

Size of the database (number of individuals) [500-1000[individuals

Details of the number of individuals 1,500

Data

Database activity Data collection completed

Type of data collected Clinical data
Biological data

Clinical data (detail)	Direct physical measures Medical registration
Details of collected clinical data	History, drug intake, DAS28 score, comorbidities such as: Severe infection, cancer, infusion reactions, pregnancy, gastrointestinal perforation, cardiovascular events, cytopenia, cytolysis.
Biological data (detail)	Rheumatoid factor, ACPA
Presence of a biobank	No
Health parameters studied	Health event/morbidity Health care consumption and services
Care consumption (detail)	Medicines consumption
Procedures	
Participant monitoring	Yes
Details on monitoring of participants	at 3 and 6 months, then every 6 months for 5 years.
Links to administrative sources	No
Promotion and access	
Promotion	
Link to the document	http://www.ncbi.nlm.nih.gov/pubmed/?term=regate+AND+%28Morel[author]+OR+Sibilia[author]%29
Description	List of publications in Pubmed
Access	
Terms of data access (charter for data provision, format of data, availability delay)	Contact the scientist in charge.
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only