Utilisation disease-modifying anti-rheumatic drugs (DMARDs) used for the treatment of rheumatoid arthritis: protocol for a multi-database real-world cohort study

First published: 24/01/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS33253

Study ID

33254

DARWIN EU® study

No

Study countries

Austria

Belgium

Estonia

France

Germany

Japan

Spain

United Kingdom

United States

Study description

There are no studies to date that have compared international drug utilisation of rheumatoid arthritis patients receiving DMARDs and long-term sequential prescribing following initial prescription. A drug utilisation study (DUS) on the use of DMARDs would therefore provide insights into real-world practice in RA.By means of a retrospective cohort study using routine-collected health care data which has been mapped to the Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM), we aim to characterise the prescribing/dispensing of first line DMARDs with regard to: i) type of first DMARD being prescribed during the the first year and during the first five years following the diagnosis of RAii) utilisation of second line DMARDs during the first year and during the first five years following RA diagnosisiii) proportion of patients not being treated with first line DMARDs following RA diagnosisiv) characterize use of DMARDs over calendar time.The start date for the study period will be from 01/01/2000 or from the start of the first available observation periods in the data source with sufficient data whichever comes last. The study period will end at the latest on 31/12/2018 for all data sources. The study population consists of DMARD naive rheumatoid arthritis (RA) patients. Patients are required to be ≥ 18 years at index and have ≥ 365 days of prior continuous observation and 365 days post-index time. DMARD drug exposure (biologic DMARD, tsDMARD, or csDMARD) will be identified from the drug exposure table in the CDM. Study participants demographics (gender, age, observation time prior to their index date, and their index year and month) will

be idenfied.Both the incidence and prevalence of RA will be calculated as well as the proportion of patients treated with DMARDs. A sunburst diagram will be produced to describe the proportion of DMARD treatments for each treatment sequence observed in the target population.

Study status

Ongoing

Research institutions and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/05/2025

Institution **Educational Institution** **Laboratory/Research/Testing facility** **Not-for-profit** **ENCePP partner**

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

University of Manchester

United Kingdom

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution

Johnson & Johnson

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Erasmus MC Rotterdam, The Netherlands, NDORMS, University of Oxford Oxford, UK, IEETA/DETI, University of Aveiro Aveiro, Portugal, Centre for Epidemiology Versus Arthritis, University of Manchester Manchester, UK, Janssen Research and Development Titusville, USA, Columbia University, New York New York, USA

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Prieto Dani

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2019

Actual: 01/10/2019

Study start date

Planned: 13/01/2020

Actual: 13/01/2020

Data analysis start date

Planned: 15/01/2020

Actual: 15/01/2020

Date of final study report

Planned: 31/03/2020

Sources of funding

- Other

More details on funding

OHDSI

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

The main objectives of this study are to investigate:- the type of first DMARD being prescribed (first year and first 5 years)- utilisation of second line DMARDs (first year and first 5 years)- proportion of patients not being treated with first line DMARDs - characterize use of DMARDs over calendar time

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M01C) SPECIFIC ANTIRHEUMATIC AGENTS

SPECIFIC ANTIRHEUMATIC AGENTS

Medical condition to be studied

Rheumatoid arthritis

Population studied

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

300000

Study design details

Data analysis plan

This study will describe the treatment pathways of patients diagnosed with RA. The analysis will calculate the aggregate summary statistics for each RA cohort to determine the treatment pathway for each of the DMARDs in the study For each of the cohorts, a sunburst diagram will be produced to describe the proportion of DMARD treatments for each treatment sequence observed in the target population. The sunburst diagram will have a maximum of 10 levels. The incidence and prevalence of RA will be calculated for each database in the

study and expressed as number of new patients diagnosed with RA/1,000 individuals (for incident) or the number of patients with RA (prevalent)/1,000 individuals. This will be done by year, stratified by age and gender. Descriptive statistics will be used (absolute count, proportion, mean & median)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Signed checklist for study protocols

ENCePPChecklistforStudyProtocols_EUPAS33253.pdf (207.1 KB)

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

THIN, IPCI, SIDIAP, IMS LifeLink:Longitudinal Prescription Data - Bel, IMS LifeLink: Longitudinal Prescription Data - Aus

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No