

Big data analysis on treatment patterns and safety events in patients identified as rheumatoid arthritis according to International Statistical Classification of diseases and Related Health Problems (RA SE)

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Study

Finalised

Administrative details

EU PAS number

EUPAS35782

Study ID

38440

DARWIN EU® study

No

Study countries

Study description

RA SE study (Protocol #A3921283) is a non-interventional, retrospective cohort study, using Health insurance claim data that exist in anonymized structured format by the time of study start. The objectives of this study are to identify the treatment patterns and safety events in patients identified as rheumatoid arthritis by using the representative secondary data in Korea. This study has been conducted up to the final results as a local non-PASS study without taking over the final confirmation for the study scope as a non-PASS since 05-Aug-2017. However, as opening Quality Event (T1 PR ID: 2163843), this study is following the procedure for PASS.

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Soo-Hyun Lee

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 09/09/2017

Study start date

Actual: 01/11/2017

Data analysis start date

Actual: 10/05/2019

Date of final study report

Planned: 31/10/2020

Actual: 07/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

[A3921283 Protocol_ver4.0_PASS_eng_clear.pdf](#) (630.85 KB)

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

The objectives of this study are to identify the treatment patterns and safety events (Pneumonia, Herpes zoster, Tuberculosis, Malignancy) in patients identified as rheumatoid arthritis according to International Statistical Classification of diseases and Related Health Problems by using the representative secondary data in Korea.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Rheumatoid arthritis

Osteoarthritis

Population studied

Short description of the study population

The subjects of this study shall select and analyze patients who meet the following inclusion and exclusion criteria among the recent five-year data provided by the Health Insurance Review and Assessment Service.

Inclusion criteria

Patients must meet all of the following inclusion criteria to be eligible for inclusion in the study:

1. RA cohort group 1: Patients who have been diagnosed with rheumatoid arthritis by ICD code in the last four years and treated with bDMARDs or tsDMARD with or without csDMARDs treatment.
2. RA cohort group 2: Patients who have been diagnosed with rheumatoid arthritis by ICD code in the last four years and treated with csDMARDs without bDMARDs or tsDMARD treatment.
3. OA cohort group: Patients who have been diagnosed with osteoarthritis by ICD code in the last four years and used at least one of the osteoarthritis drugs for more than three months.
4. Select RA cohort group 2 and OA cohort group with the same age and gender

distribution as that of RA cohort group 1.

Exclusion criteria

Patients meeting any of the following criteria will not be included in the study:

1. RA cohort group 1: Patients who have been diagnosed with rheumatoid arthritis by ICD code and treated with bDMARDs or tsDMARDs for the previous one year from the time of enrollment.
 2. RA cohort group 2: Patients who have been diagnosed with rheumatoid arthritis by ICD code and treated with csDMARDs, bDMARDs or tsDMARDs for the previous one year from the time of enrollment.
 3. OA cohort group: Patients who have been diagnosed with osteoarthritis by ICD code and used at least one of the osteoarthritis drugs for more than three months for the previous one year from the time of enrollment.
 4. All cohort groups: Persons who have developed Infection (pneumonia, herpes zoster, tuberculosis, cutaneous abscess, cellulitis), Malignancy for the previous one year from the time of enrollment.
 5. All cohort groups: Exclude if at least one month follow-up period is not met.
 6. Exclude clinic-grade from the classification of medical care institutions
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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)
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Special population of interest

Immunocompromised

Estimated number of subjects

16122

Study design details

Outcomes

First, identify the treatment pattern of patients diagnosed with rheumatoid arthritis in the last four years. Second, identify the incidence of safety events and the scale of prevalence in patients diagnosed with rheumatoid arthritis in the last four years.

Data analysis plan

The basic characteristics and basic clinical data of the subjects are summarized in a tabular format. Continuous data basically present mean, standard deviation, median, quartile ranges, minimum and maximum values, and categorical data present absolute and relative frequencies and corresponding percentages. To identify treatment patterns, the mean and standard deviation of treatment duration are calculated. Calculate the incidence of safety events and confidence intervals in patients diagnosed with the target diseases. The Kaplan-Meier method and a stratified Cox's PH regression analysis are used to estimate the cumulative incidence (CI) of safety events and to compare the differences in the incidence of safety events among cohort groups.

Documents

Study results

[A3921283_RA_SE_Study_Report_Abstract_06Nov2020.doc.pdf](#) (268.79 KB)

[A3921283_RA_SE_Study_Report_fully approved_07Dec2020.pdf](#) (2.82 MB)

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.

Data sources

Data source(s), other

Health Insurance Review and Assessment Service database (HIRA DB)

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

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