A Prospective Observational Study within the Corrona International Registry to Evaluate Safety and Effectiveness of Tofacitinib and Biologic Disease Modifying Antirheumatic Drugs in Japan among Patients Treated for Moderately to Severely Active Rheumatoid Arthritis

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/44699

EU PAS number

EUPAS13155

Study ID

44699

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This project has been terminated due to lack of participation of subjects in the registry. No study report or publications will be made for this project.

Study status

Finalised

Research institutions and networks

Institutions

Pfizer

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Institution

Contact details

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Study contact

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Primary lead investigator

Edith Owens

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/06/2015

Actual: 17/06/2015

Study start date

Planned: 21/06/2016

Actual: 21/06/2016

Data analysis start date

Actual: 21/06/2016

Date of interim report, if expected

Actual: 21/06/2016

Date of final study report

Planned: 30/09/2023

Actual: 29/10/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Pfizer

Study protocol

A3921256_PROTOCOL_V1.0_01FEB2016.pdf(661.86 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objectives of this study are to characterize patients prescribed tofacitinib, TNF bDMARDs, non-TNF bDMARDS or methotrexate (MTX) and to evaluate safety endpoints associated with these therapies within the Japanese clinical practice setting via: 1. Evaluation of baseline characteristics 2. Evaluation and comparison of incidence rates of selected adverse events of interest.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

XELJANZ

Medical condition to be studied

Rheumatoid arthritis

Population studied

Short description of the study population

This study will recruit patients from approximately 40 clinical sites from a broad geographic distribution in Japan. Enrollment will consist of four (4) cohorts of 500 patients each segmented by drug class. There are no enrollment restrictions other than initiation of an eligible medication at the time of enrollment. Each cohort will be open to recruiting at registry initiation and will close when the patient cap of 500 patients is reached.

Inclusion criteria

To be eligible for enrollment into the Corrona Japan RA Registry, a subject must satisfy all of the following Inclusion Criteria:

1) The subject must be diagnosed with rheumatoid arthritis according to the 1987 ACR or the ACR/EULAR 2010 Rheumatoid Arthritis Classification Criteria

2) The subject must be at least 18 years of age or older (age ≥ 18 years)

3) The subject must be able and willing to provide written consent

4) The subject must be prescribed or switching to an eligible medication (Table 1) for the first time ever at the Enrollment Visit. History of or concomitant treatment with other eligible medications does not exclude a subject from enrollment.

Exclusion criteria

There are no exclusion criteria for this study.

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)

Special population of interest

Immunocompromised

Estimated number of subjects

2000

Study design details

Outcomes

The primary outcomes are incidence rates of selected adverse events including but not limited to, hospitalized infections, malignancies and cardiovasular events. Secondary objectives include evaluation of real-world clinical effectiveness including Clinical Disease Activity Index and Disease Activity Score-28 and patient reported outcomes including a Pain visual analogue scale, Health Assessment Questionnaire-Disability Index, Work Productivity and Activity Impairment, EuroQol 5D and Healthcare Resource Utilization Questionnaire.

Data analysis plan

The primary summary of event rates will be time to first event based on an index date defined for each population. Time to first event or survival analysis allows an analytic framework for estimation, adjustment for possible confounders and comparison between treatment groups. This approach also allows for variable amount of follow-up and does not assume a constant risk over time. Within this framework, the total number of years of patient follow-up will be computed by total time up to an event or up to last follow-up as well as

the total number of events (or in survival terminology, failures). The number of events (failures) divided by total person-years of follow-up will result in the event rate. Rates will be expressed as events/100 person-years of follow-up. Raw event numbers will also be reported.

Data management

Data sources

Data sources (types)

Disease registry

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