A Multinational, Prospective, Observational Study of the Effectiveness, Healthcare Resource Utilization and Costs in Patients with Rheumatoid Arthritis Receiving Baricitinib, Targeted Synthetic or Biologic Disease-Modifying Therapies (RA-BE-REAL)

First published: 08/08/2018

Last updated: 02/04/2024

Study Planned

Administrative details

EU PAS number

EUPAS25164

Study ID

25165

DARWIN EU® study

No

Study countries

- [ ] Australia
- [ ] Brazil
- [ ] Canada
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Saudi Arabia
- [ ] Spain
- [ ] United Kingdom

Study description

This is a prospective noninterventional 2-cohort study. Cohort A comprises patients with rheumatoid arthritis (RA) starting baricitinib for the first time at any point in the treatment algorithm, and Cohort B comprises patients starting treatment with any other targeted synthetic disease-modifying antirheumatic drug (tsDMARD), or a biologicaldisease-modifying antirheumatic drug (bDMARD) for the first time at any point in the treatment algorithm. The aim of the study is to define a patient profile of patients with RA starting baricitinib, other tsDMARDs, or bDMARDs for the first time, describing their patient characteristics as well as clinical and patient-reported outcomes (includinghealth related quality of life HRQOL and patient’s assessment of pain), healthcare resource utilization (HRU) and costs. The study will also describe how these treatments are used in a real-world setting by assessing treatment patterns.

Study status

Planned

Research institutions and networks

Institutions

Syneos Health

United Kingdom

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Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Walid Fakhouri

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/01/2018

Study start date

Planned: 29/09/2018

Date of final study report
Planned: 01/07/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly & Company

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:

Effectiveness study (incl. comparative)

Main study objective:

To assess, within each cohort, the time to all-cause discontinuation of treatment, specifically discontinuation rates at 24 months, ie, the rate of patients who discontinued their initial baricitinib, tsDMARD, or bDMARD treatment.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

BARICITINIB

TOCILIZUMAB

ADALIMUMAB

GOLIMUMAB

ETANERCEPT

CERTOLIZUMAB PEGOL

ABATACEPT

INFLIXIMAB

RITUXIMAB

TOFACITINIB

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

1840

Study design details

Outcomes

Treatment discontinuation rates at 24 months, Throughout the study: reasons for discontinuation, disease activity (Clinical Disease Activity Index, CDAI), physical functioning (Health Assessment Questionnaire-Disability Index, HAQ-DI), HRQOL (the European Quality of Life-5 Dimensions-5-Level, EQ-5D-5L), patients' assessment of pain (Pain VAS), Healthcare resource use (HRU) and associated costs, number of work days missed because of RA.

Data analysis plan

All analyses will be by treatment cohort. The proportion of patients who discontinued treatment at 24 months including 95% CIs will be provided.Time to discontinuation will be estimated by Kaplan-Meier analysis. Descriptive statistics will be presented for the patient characteristics and based on the observed values of patients at each time point for CDAI, HAQ-DI, EQ-5D-5L, and the patient’s assessment of pain. For HRU, total quantity of resources used will be calculated as the sum of resources. Costs for the treatment during the 3 years after initiation of treatment will be calculated based on the HRU data, and using publicly available unit costs.Total direct medical costs during the 3 years will be calculated based on medication costs and HRU costs. For each cohort, the total direct medical cost will be described overall (all resources combined) and separately for each type of cost. Indirect costs (work days missed due to RA) will be calculated.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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