Long-term comparative safety cohort studies of upadacitinib (Rinvoq™) use for the treatment of RA in Europe

First published: 12/02/2021

Last updated: 02/07/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47968

EU PAS number

EUPAS39217

Study ID

47968

DARWIN EU® study

No

Study countries

☐ Denmark

- [ ] Germany
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom (Northern Ireland)

Study description

The purpose of this study is to evaluate and characterise the important identified and potential risks of upadacitinib (Rinvoq™) and missing information on the safety of upadacitinib, as described in the European Union (EU) Risk Management Plan (RMP) for Rinvoq™ (upadacitinib). This study aims to evaluate the long-term safety of upadacitinib among patients with RA receiving routine clinical care.

Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

- [ ] Denmark

First published: 20/07/2021

Last updated: 02/04/2024

Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

Clinical Trial AbbVie

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/11/2020

Actual: 25/11/2020

Study start date

Planned: 01/01/2020

Actual: 15/06/2021

Date of final study report

Planned: 31/03/2030

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p19150-protocol abstract-pmos_Redacted.pdf(218.99 KB)

P19150-protocol-pmos-v3-Abstract_Redacted.pdf(279.11 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Other study registration identification numbers and links

P19-150

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The purpose of this study is to evaluate and characterise the important identified and potential risks of upadacitinib (Rinvoq™) and missing information on the safety of upadacitinib, as described in the European Union (EU) Risk Management Plan (RMP) for Rinvoq™ (upadacitinib). This study aims to evaluate the long-term safety of upadacitinib among patients with RA receiving routine clinical care.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

RINVOQ

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

12000

Study design details

Outcomes

To describe and compare (when possible) the incidence rates of the following important risks: serious and opportunistic infections (including herpes zoster and tuberculosis TB), malignancies, major adverse cardiovascular events (MACE), venous thromboembolism (VTE), mortality, gastrointestinal (GI) perforations, and liver injury (including drug-induced liver injury DILI. To describe the incidence rates among patients with missing information on the safety of upadacitinib, including the very elderly (≥ 75 years of age), and when data are available, in patients with moderate hepatic impairment, patients with severe renal impairment, and patients with evidence of chronic infection with hepatitis B or hepatitis C.

Data analysis plan

Analyses will be conducted separately for each outcome in each registry and will include descriptive analyses of baseline characteristics and cumulative rates of study endpoints (i.e. events of special interest or serious adverse events SAEs, depending on registry) for each exposure cohort. Comparative

analyses will be performed to evaluate whether upadacitinib treatment is associated with an increased risk of outcomes of interest relative to control cohorts.

Data management

Data sources

Data source(s)

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

Data source(s), other

BSRBR - Rheumatic and Musculoskeletal conditions

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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