Drug utilisation study of upadacitinib (Rinvoq™) in Europe to evaluate the effectiveness of additional risk minimisation measures

First published: 12/02/2021

Last updated: 02/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/47974

EU PAS number

EUPAS39211

Study ID

47974

DARWIN EU® study

No

Study countries

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

Study description

This study aims to characterise the use of upadacitinib (Rinvoq™) in routine clinical care, including describing baseline characteristics of individuals with rheumatoid arthritis exposed to upadacitinib relative to individuals with rheumatoid arthritis exposed to other systemic treatments. This study also aims to evaluate the effectiveness of additional risk minimisation measures.

Study status

Ongoing

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

- [ ] Denmark

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Institution | Educational Institution | ENCePP partner

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure 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: 30/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p20199-protocol abstract-pmos_Redacted.pdf(183.53 KB)

P20-199_Protocol v2.0_Abstract_Redacted.pdf(155.12 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

P20-199

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

This study aims to characterise the use of upadacitinib (Rinvoq™) in routine clinical care.

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

2400

Study design details

Outcomes

To describe the baseline characteristics of new users of upadacitinib (e.g. demographics, medical history, medical condition associated with upadacitinib use, and concomitant medication use), and in a similar manner, to describe new users of a selected biologic disease-modifying anti-rheumatic drug (bDMARD) for comparison. Evaluate the effectiveness of additional risk minimisation measures (aRMMs): quantify occurrence of upadacitinib in patients at high risk for a VTE and in patents currently being treated for active TB, quantify number of patients pregnant at time of initiation/become pregnant while taking upadacitinib, describe prescribing doctors' adherence to recommendations for patient screening/lab monitoring.

Data analysis plan

All analyses will be descriptive, no statistical tests will be performed. Analyses will be performed separately for each registry and exposure group (i.e. upadacitinib cohort and selected bDMARD cohort). Baseline patient characteristics will be assessed at study drug initiation. To address important safety information communicated in the healthcare professional educational material and patient alert card, outcome indicators at the time of initiation will be evaluated in the upadacitinib cohort. Additional outcome indicators will be assessed in the upadacitinib cohort during their continuous treatment.

Data management

Data sources

Data source(s)

British Society for Rheumatology Biologics Register for Rheumatoid Arthritis

Data source(s), other

ARTIS Sweden, DANBIO Denmark, BIOBADASER Spain, RABBIT Germany

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