Drug Utilization Study Evaluating Additional Risk Minimisation Measures for Upadacitinib in the Treatment of Ulcerative Colitis in Europe

First published: 16/01/2024

Last updated: 25/06/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/199004

EU PAS number

EUPAS107885

Study ID

199004

DARWIN EU® study

No

Study countries

☐ Denmark

☐ Spain

☐ Sweden

Study description

The study aims to evaluate the use of upadacitinib in patients with ulcerative colitis (UC) in routine clinical care in Denmark, Sweden, and Spain.

The study objectives are:

1. To describe the baseline characteristics of patients with UC who are new users of upadacitinib.
2. To the extent measurable, evaluate healthcare utilization in routine clinical care as indicator of physician adherence to the additional risk minimisation measures (aRMMs) among patients with UC who are new users of upadacitinib, by:

a) Quantifying the compliance to recommendations for posology (average daily dose) and duration of use;

b) Quantifying the compliance to recommendations for the use among patients who have risk factors for gastrointestinal (GI) perforation, malignancy, major adverse cardiovascular events (MACE), venous thromboembolic events (VTE), and serious infections;

c) Quantifying the compliance to the recommendations for the use among patients aged 65 years and older;

d) Quantifying the compliance to the recommendations for contraindicated use including pregnancy and active tuberculosis (TB);

e) Quantifying the compliance to recommendations for patient screening and laboratory monitoring prior to and during upadacitinib treatment (Denmark and Spain only).

3. To describe the changes in the utilization of upadacitinib following the

implementation of revised aRMMs from the Article 20 referral procedure (Sweden only), specifically:

a) Describe the use of upadacitinib among patients with risk factors for VTE, MACE, malignancy, and serious infections;

b) Describe the use of upadacitinib among patients aged 65 years and older;

c) Describe the use of higher maintenance dose of upadacitinib 30 mg.

Study status

Ongoing

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution | **Educational Institution** | **Laboratory/Research/Testing facility** | **Not-for-profit** | **ENCePP partner**

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

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Johan Reutfors

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 25/08/2022

Study start date
Planned: 22/06/2023

Actual: 14/12/2023

Data analysis start date
Planned: 31/03/2027

Date of final study report
Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p24344-protocol-pmos-v1.2_10Nov2023_Redacted 2_21Jun2024.pdf(12.27 MB)

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

P24-344

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

To describe the baseline characteristics and, to the extent measurable, evaluate healthcare utilization in routine clinical care as indicator of physician adherence to the aRMMs among patients with UC who are new users of upadacitinib. To describe the changes in the utilization of upadacitinib following the implementation of revised aRMMs from the Article 20 referral procedure (in Sweden only).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

RINVOQ

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

UPADACITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AA44) upadacitinib

upadacitinib

Medical condition to be studied

Colitis ulcerative

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

2000

Study design details

Outcomes

Indicators of physician adherence to the additional risk minimisation measures related to malignancy, MACE, GI perforation, VTE, serious infections, contraindication and posology, Baseline characteristics

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Data analysis plan

All analyses will be descriptive; no statistical tests will be performed. Proportions of the outcome variables will be assessed prior to upadacitinib initiation, at upadacitinib initiation and during follow-up, depending on the outcome variable being reported.

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DeclarationofInterests-Annex5_P24-344 upa UC DUSRMM_231219_JR.pdf(105.92 KB)

Composition of steering group and observers

EUPAS107885-108467.pdf(60.64 KB)

Signed code of conduct

ENCePPCoCAnnex3_DeclarationofcompliancewiththeENCePPCodeofConduct_JR.pdf (57.54 KB)

Signed code of conduct checklist

ENCePPCoCAnnex2_ChecklistofCodeofConduct_upa UC RMM_JR.pdf(549.14 KB)

Signed checklist for study protocols

Signed ENCePP checklist protocol_upa UC RMM-05sep2023_JR.pdf(146.61 KB)

Data sources

Data source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

- SWIBREG, Sweden
- SMINET, Sweden
- Swedish National Registers
- ENEIDA, Spain

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Other

Data sources (types), other

Pharmacy dispensing records, quality register, medical chart abstraction

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