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

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Study | Planned

Administrative details

Contact details

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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
Planned

Research institution 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
ENCePP partner
Educational Institution

RTI Health Solutions (RTI-HS)

France
Spain
Sweden
United Kingdom
United Kingdom (Northern Ireland)
United States
First published: 21/04/2010
Last updated
19/02/2024

Institution
ENCePP partner
Not-for-profit

Study timelines

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

Data collection
Planned:
31/03/2024

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

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

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 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 follo

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
200000012116
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

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)

Data sources

Data source(s)
Danish registries (access/analysis)
National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other
SWIBREG Sweden, SMINET Sweden, Swedish national registers, ENEIDA Spain

Data sources (types)
Administrative data (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