Drug Utilization Study Evaluating Additional Risk Minimization Measures for Upadacitinib in the Treatment of Atopic Dermatitis in Europe

First published: 25/06/2024

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000166

EU PAS number

EUPAS49233

Study ID

1000000166

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Germany
- [ ] Spain
- [ ] Sweden

Study description

The study aims to evaluate the use of upadacitinib (RINVOQ®) in individuals with AD in routine clinical care in Denmark, Germany, Spain, and Sweden. The study objectives are:

1. To describe the baseline characteristics of individuals with AD who are new users of upadacitinib.
2. To the extent measurable, evaluate healthcare utilization in routine clinical care as an indicator of physician adherence to the aRMMs among individuals with AD who are new users of upadacitinib, by:

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

b. Quantifying the compliance to recommendations for the use among individuals who have risk factors for GI perforation, serious infections, malignancy, MACE, and VTE.

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 TB.

e. Quantifying the compliance to recommendations for patient screening and laboratory monitoring prior to and during upadacitinib treatment (Denmark, Germany, 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, 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 upadacitinib 30 mg.

Study status

Ongoing

Research institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

Last updated: 26/02/2024

Institution **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**

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

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain

First published: 05/10/2012

Last updated: 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | 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

Planned: 15/11/2021

Actual: 08/12/2021

Study start date

Planned: 25/04/2024

Actual: 25/04/2024

Data analysis start date

Planned: 30/06/2024

Date of final study report

Planned: 30/09/2026

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p21825-protocol-pmos-v3.2_Redacted.pdf(2.04 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

P21-825

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

The study is a drug utilization, descriptive, non-interventional, population-based, cohort study of new users of upadacitinib (RINVOQ®) for the treatment of AD identified in electronic healthcare data from four European countries: Denmark, Germany, Spain, and Sweden.

Main study objective:

The objectives are to describe the baseline characteristics of individuals with AD who are new users of upadacitinib, and to the extent measurable, evaluate healthcare utilization in routine clinical care as an indicator of physician adherence to the aRMMs among individuals with AD 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.

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

Dermatitis atopic

Population studied

Short description of the study population

The study population consists of all individuals with AD registered in the databases in the four countries who are treated with upadacitinib. Each individual will be followed from the initiation of upadacitinib to the end of the study period (i.e., 31 December 2024), study withdrawal, or death.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Hepatic impaired

Pregnant women

Renal impaired

Estimated number of subjects

3000

Study design details

Setting

The study is based on electronic healthcare data from Denmark, Germany, Spain, and Sweden covering populations of approximately 5.8 million, 25 million, 5.8 million, and 10.2 million people, respectively.

Outcomes

Indicator of physician adherence to the additional risk minimisation measures related to malignancy, MACE, GI perforation, VTE, serious and opportunistic infections including HZ, contraindications (pregnancy, and active TB) and posology.

To describe the baseline characteristics of new users of upadacitinib.

Data analysis plan

This will be a descriptive study. Upon upadacitinib initiation, baseline characteristics of individuals will be assessed. Proportions of the aRMM outcome variables will be assessed prior to upadacitinib initiation, at upadacitinib initiation and during continuous treatment of upadacitinib, depending on the outcome variable being reported. The proportion of the outcome variables will be calculated as the number of individuals for each specific outcome variable over the total number of individuals considered for that specific outcome.

Utilization of upadacitinib will be stratified by the time period before and after the implementation of the revised aRMMs from the Article 20 referral procedure as well as by Coronavirus disease 2019 (COVID-19) pandemic time periods (COVID-19 pandemic and non-COVID-19 pandemic).

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DoIForm_v1.6_Upa AD RMM_JR.pdf(454.8 KB)

Composition of steering group and observers

Composition of Steering Group and Observers.pdf(60.64 KB)

Signed code of conduct

Annex3_Declaration-Upa AD RMM_signed.pdf(241.69 KB)

Signed code of conduct checklist

Annex2_Checklist_Upa AD RMM_signed.pdf(1.58 MB)

Signed checklist for study protocols

Signed ENCePP checklist for Upa AD RMM v1.0 Study Protocol.pdf(128.96 KB)

Data sources

Data source(s)

Sweden National Cancer Register / Cancerregistret

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Danish registries (access/analysis)

Data source(s), other

The Swedish National Patient register

The Swedish Cause of Death Register

Swedish Medical Birth Register

SMINET

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Drug dispensing/prescription data

Laboratory tests and analyses

Population registry

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