Cohort Study of Long-term Safety of Upadacitinib in the Treatment of Atopic Dermatitis in Denmark and Sweden

First published: 11/07/2023

Last updated: 19/05/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS49230

Study ID

106312

DARWIN EU® study

No

Study countries

- ☐ Denmark
- ☐ Sweden

Study description

The purpose of this study is to evaluate and characterise the important identified and potential risks of upadacitinib and missing information on the safety of upadacitinib, as described in the EU RMP for upadacitinib for the treatment if AD.

Primary objective: To describe and if possible compare the incidence of Malignancy (excluding NMSC) including malignancy by type, NMSC, MACE, VTE, serious infections (including OI), HZ, EH/ KVE, TB, GI perforations, DILI, fractures and all-cause mortality, in adolescent and adult individuals with AD treated with upadacitinib, relative to those treated with other selected systemic AD treatments.

The secondary objectives are: To describe the incidence of the safety outcomes mentioned under primary objectives in upadacitinib users by: dose of upadacitinib (15 mg and 30 mg), age group (adolescents 12-17 years, 18-64 years, 65-74 years and ≥ 75 years) at the time of upadacitinib initiation, history of moderate hepatic impairment at the time of upadacitinib initiation, history of chronic infection with hepatitis B virus or hepatitis C virus at the time of upadacitinib initiation, and history of severe renal impairment at the time of upadacitinib initiation.

If a suitable comparator is identified: To describe the incidence of the safety outcomes mentioned under primary objectives in adolescent and adult individuals with AD treated with other select systemic AD treatments by: age group (adolescents 12-17 years, 18-64 years, 65-74 years and ≥ 75 years) at the time of treatment initiation, history of moderate hepatic impairment at the time of treatment initiation, history of chronic infection with hepatitis B virus (HBV) or hepatitis C virus (HCV) at the time of treatment initiation, and history of severe renal impairment at the time of treatment initiation.

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**

Contact details

Study institution contact

Johan Reutfors johan.reutfors@ki.se

Study contact

johan.reutfors@ki.se

Primary lead investigator

Johan Reutfors

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/12/2021

Study start date

Planned: 10/02/2022

Actual: 08/06/2023

Date of interim report, if expected

Planned: 31/12/2028

Date of final study report

Planned: 31/12/2033

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p20390-protocol-pmos-v4-0-Redacted.pdf(2.18 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

P20-390

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To describe and if possible compare the incidence of malignancy (excluding NMSC), including malignancy by type, NMSC, MACE, VTE, serious infections (incl. OI), HZ, EH/KVE, active TB, GI perforation, drug-induced liver injuries, fractures and all-cause mortality in adolescent and adult individuals with Atopic dermatitis (AD) treated with upadacitinib or other selected systemic AD treatments.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

UPADACITINIB

Anatomical Therapeutic Chemical (ATC) code

(L04AF03) upadacitinib

upadacitinib

Medical condition to be studied

Dermatitis atopic

Population studied

Age groups

Adolescents (12 to < 18 years)

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)

Special population of interest

Hepatic impaired

Renal impaired

Estimated number of subjects

10000

Study design details

Outcomes

Malignancy (excluding non-melanoma skin cancer NMSC), including malignancy by type, NMSC, major adverse cardiovascular events, venous thromboembolic events, serious infections (including opportunistic infections), herpes zoster, eczema herpeticum/Kaposi’s varicelliform eruption, active tuberculosis, gastrointestinal perforations, drug-induced liver injuries, fractures and all-cause mortality.

Data analysis plan

Descriptive analyses will be conducted to characterize the users and the real-world utilization of upadacitinib and other select systemic AD treatments to assess suitability of treatment groups as potential comparators to the upadacitinib cohort.

Person-years at risk, number of safety outcomes and crude incidence rates for upadacitinib will be reported.

If suitable/comparable treatment cohorts can be identified, crude incidence rates for comparator treatments and hazard ratios between upadacitinib and comparator cohorts will be provided as well.

Cox proportional hazards model adjusting for confounding will be used to calculate hazard ratios.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

DoIs combined_upa AD PASS.pdf(2.9 MB)

Composition of steering group and observers

EUPAS49230-105777.pdf(60.64 KB)

Signed code of conduct

Annex3_Declaration-Upa AD PASS_signed.pdf(247.23 KB)

Signed code of conduct checklist

Annex2_Checklist-Upa AD PASS_signed.pdf(1.56 MB)

Signed checklist for study protocols

Signed ENCePP checklist for Upa AD PASS v1.0 Study Protocol.pdf(137.81 KB)

Data sources

Data source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

The Swedish National Patient Register Sweden

The Swedish Cause of Death Register Sweden

The Swedish Cancer Register Sweden

The contagious disease register Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

Pharmacy dispensing records

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