A post-marketing registry-based prospective cohort study of long-term safety of risankizumab in Denmark and Sweden

First published: 22/02/2021

Last updated: 26/03/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS39351

Study ID

48467

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] Sweden

Study description

The aim of the study is to estimate the risk of malignancy, MACE, serious infections, serious hypersensitivity reactions and incident hepatitis B and C among individuals with psoriasis who were exposed to risankizumab, relative to individuals with psoriasis exposed to other systemic treatments (biologics and non-biologics) divided into three subgroups, other IL-inhibitors treatment (excluding risankizumab), TNF-α inhibitor treatment, and non-biologic systemic treatment.

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**

The Danish National University Hospital Denmark

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: 29/09/2020

Actual: 29/09/2020

Study start date

Planned: 31/12/2021

Actual: 07/02/2022

Date of final study report

Planned: 31/12/2034

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

p19633-protocol abstract-pmos-04sep2020_Redacted.pdf (180.77 KB)

p19633-protocol-V1.6_Abstract_Redacted.pdf (693.4 KB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

P19-633

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:

The objectives of the study are to estimate the risk of the following events in individuals with psoriasis exposed to risankizumab relative to individuals with psoriasis exposed to other systemic psoriasis treatments: overall malignancy excluding NMSC, NMSC, MACE, serious infections, serious hypersensitivity reactions, incident acute and chronic hepatitis B and hepatitis C.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SKYRIZI

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

RISANKIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AC18) risankizumab

risankizumab

Medical condition to be studied

Psoriasis

Psoriatic arthropathy

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

45000

Study design details

Outcomes

The study outcomes will be malignancies, MACE, serious infections, serious hypersensitivity reactions and incident hepatitis B and C.

Incident malignancy will be identified via the linked national cancer registers in each country.
The other outcomes will be captured through inpatient and specialist outpatient diagnoses in the patient registers.

Data analysis plan

Appropriate statistical analyses in an active-comparator design will be used.
Cox proportional hazards model will be used to calculate hazard ratios.
Propensity score matching will be used to adjust for confounding.

Documents

Study, other information

DoI_all combined.pdf (295.47 KB)

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.

Data sources

Data source(s)

Danish registries (access/analysis)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Sweden National Cancer Register / Cancerregistret

Swedish Cause of Death Register

Data source(s), other

The Swedish National Patient Register Sweden

Swedish Registry for Systemic Psoriasis Treatment (PsoReg)

Data sources (types)

Cancer registry

Death registry

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