An Observational Longitudinal Post-authorization Safety Study of STELARA® in the Treatment of Psoriasis and Psoriatic Arthritis: Analysis of Major Adverse Cardiovascular Events (MACE) using Swedish National Health Registers (QUANTIFY STELARA MACE)

First published: 07/02/2023

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Study Finalised

Administrative details

EU PAS number

EUPAS49873

Study ID

103700

DARWIN EU® study

No

Study countries

Sweden

Study status

Finalised

Research institutions and networks

Institutions

Quantify Research

Sweden

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jonas Banefelt

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/10/2022

Study start date
Actual: 01/07/2009

Date of final study report
Planned: 30/06/2023

Actual: 12/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Janssen-Cilag International NV

Study protocol

29Sep2023-Quantify Protocol Redacted.pdf (3.57 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)

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

Estimate and compare the risk of MACE in PsO and PsA patients initiating treatment with ustekinumab relative to patients initiating treatment with etanercept in routine clinical practice in Sweden.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

USTEKINUMAB

ADALIMUMAB

ETANERCEPT

SECUKINUMAB

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

11.600

Study design details

Outcomes

MACE (composite outcome of myocardial infarction, ischemic stroke, and CV death), as measured by: Stabilized propensity score-weighted hazard ratios (primary endpoint), Cumulative incidence, unadjusted (secondary endpoint), Incidence rates, unadjusted (secondary endpoint). Incidence rates will also be estimated for each component of MACE, Estimate and compare risk of MACE in PsO and PsA patients initiating treatment with ustekinumab vs adalimumab, ustekinumab vs secukinumab, adalimumab vs etanercept, secukinumab vs etanercept in routine clinical practice in Sweden.

Data analysis plan

Patient characteristics will be reported for each cohort in the overall incident user and bionaïve population. Primary outcome of MACE will be analyzed using time-to-event methodology. Cumulative incidence and incidence rates of MACE and total amount of available FU will be reported for each cohort. Cox proportional hazards regression with stabilized IPTW by PS will be used to adjust for confounding by treatment selection. To test the robustness of the results,

additional sensitivity analysis will be performed.

Documents

Study results

27Dec2023-REDACTED_CSR-Body-PCSIMM004697-1033865_1199311.pdf (636.1 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)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

National Patient Registry (NPR) Sweden, National Patient Registry (NPR) Sweden, Cause of Death Registry (CDR) Sweden

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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