Randomized clinical trial replication and second-stage study to evaluate the risk of serious infections in biological drug users with psoriatic arthritis and psoriasis using the Italian VALORE distributed database network

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Study Ongoing

Administrative details

EU PAS number

EUPAS1000000537

Study ID

1000000537

DARWIN EU® study

No

Study countries

Italy

Study status

Ongoing

Research institutions and networks

Institutions

Pharmacology Unit - Veneto Pharmacovigilance Centre (Pharmacol UNIVR), University Hospital Verona

Italy

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Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Contact details

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Study contact

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Primary lead investigator

Andrea Spini

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2020

Study start date
Actual: 01/01/2025

Date of final study report
Planned: 30/06/2026

Sources of funding

- National competent authority (NCAs)

Study protocol

Replication EXCEED protocol_vs4.pdf (720.45 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study topic:

Human medicinal product

Study topic, other:

Biological drugs, risk of infection

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Population studied

Short description of the study population

Replication: Subjects will be included according to the following steps:
- New users of secukinumab and adalimumab (defined as no previous use of adalimumab and secukinumab before the index date, i.e., the first dispensation) will be identified.
- At least 1 year of look-back (history in the database before the index date)
- The index date must be after December 31, 2014, and before January 1, 2022.
o Rationale: The market authorization of secukinumab in Europe started on 01/2015, and the VALORE project collected data for each region at least until the end of 2022, allowing patients to be followed for at least one year after the index date (this was not true for Lazio region for which only data until 2020 were available).
- See other inclusion and exclusion criteria for cohort entry. Inclusion and exclusion criteria were adapted from the EXCEED trial as closely as possible.

Table A1 and Table A2 in the appendix show all the inclusion and exclusion criteria of the EXCEED trial with the respective emulation strategy and the flow chart of the study respectively.

Special population of interest

Other

Special population of interest, other

elderly

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 sources (types)

Administrative healthcare records (e.g., claims)

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes