Risk of serious infections with bDMARDs in psoriasis/psoriatic arthritis patients: a large-scale cohort study using the Italian VALORE Project distributed database

First published: 16/06/2023

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Study Ongoing

Administrative details

EU PAS number

EUPAS105426

Study ID

106605

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

First published: 25/10/2022

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

Sezione di Farmacologia,Dipartimento di Diagnostica e Sanità Pubblica

Several regions Italy

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gianluca Trifirò

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/01/2021

Study start date

Actual: 01/04/2023

Date of final study report

Planned: 31/12/2023

Sources of funding

- Other

More details on funding

AIFA

Study protocol

Protocollo_Severe_Infectious_Diseases_In_Dermatology_final.pdf(412.73 KB)

Protocollo_Severe_Infectious_Diseases_In_Dermatology_Nuova versione_1.pdf
(798.46 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 type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Main study objective:

To evaluate the association between the use of individual bDMARDs approved for PsO/PsA treatment and the occurrence of severe infection risk in an Italian

real-world setting in the years 2010-2021 among different drug class (TNF-alpha inhibitors, IL inhibitors, T cell modulator), using the large-scale “VALORE” project distributed database network.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ADALIMUMAB

INFLIXIMAB

ETANERCEPT

CERTOLIZUMAB

GOLIMUMAB

BRODALUMAB

IXEKIZUMAB

SECUKINUMAB

BIMEKIZUMAB

GUSELKUMAB

RISANKIZUMAB

TILDRAKIZUMAB

USTEKINUMAB

ABATACEPT

Medical condition to be studied

Psoriasis

Psoriatic arthropathy

Population studied

Age groups

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

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)

Estimated number of subjects

15000

Study design details

Outcomes

To assess the incidence of severe infection between bDMARDs in monotherapy and in combination therapy with csDMARDs and/or systemic corticosteroids.

Data analysis plan

The study aims to describe the characteristics of incident users of biologic Disease-Modifying Anti-Rheumatic Drugs (bDMARDs) using means, standard deviations, and frequencies. Differences between bDMARDs users are assessed using standardized difference (d), t-tests, and Chi-Square or Fisher tests. The primary objective is to estimate the incidence of severe infections between

different bDMARD classes (TNF alpha vs IL-inhibitors/Selective Immunosuppressive agents) using Propensity Score matching and Cox Proportional-Hazards models. The incidence will be reported per 100 person-years. Two additional objectives involve estimating the effect of bDMARD classes and combinations (bDMARDs alone vs with corticosteroids or csDMARDs) on the incidence of serious infections requiring hospitalization. These will also use Cox models, both in unmatched and matched cohorts. Sensitivity analyses will treat drug exposure as a time-dependent variable without censoring for drug switches or discontinuation

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)

Disease registry

Other

Data sources (types), other

Prescription event monitoring

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