

Drug utilization of biological drugs in patients over 65 years with Immune-mediated inflammatory diseases through the Italian VALORE network

First published: 04/10/2024

Last updated: 13/03/2025

Study

Planned

Administrative details

EU PAS number

EUPAS1000000211

Study ID

1000000211

DARWIN EU® study

No

Study countries

 Italy

Study description

This study aims to assess the utilization of TNF-alpha inhibitors, anti-interleukin, selective immunosuppressants and anti-integrins in IMIDs patients over 65 years of age to shed a light of their use in clinical practice using data from the VALORE project, specifically observing persistence to biological therapies.

Study status

Planned

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

Study institution contact

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Study contact

andrea.spini@univr.it

Primary lead investigator

Andrea Spini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2020

Study start date

Planned: 01/02/2024

Data analysis start date

Planned: 01/04/2024

Date of final study report

Planned: 31/12/0024

Study protocol

[Protocol 65+ VALORE .pdf](#) (145.95 KB)

Regulatory

Was the study required by a regulatory body?

Unknown

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

Non-EU RMP only

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

retrospective, cohort study will be performed

Main study objective:

This study aims to assess the utilization of TNF-alpha inhibitors, anti-interleukin, selective immunosuppressants and anti-integrins in IMIDs patients over 65 years of age to shed a light of their use in clinical practice using data from the VALORE project, specifically observing persistence to biological therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

ABATACEPT

ADALIMUMAB

ANAKINRA

BRODALUMAB

CERTOLIZUMAB PEGOL

ETANERCEPT

GOLIMUMAB

GUSELKUMAB

INFLIXIMAB

IXEKIZUMAB

RISANKIZUMAB

SARILUMAB

SECUKINUMAB

TILDRAKIZUMAB

TOCILIZUMAB

USTEKINUMAB

VEDOLIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA24) abatacept

abatacept

(L04AG05) vedolizumab

vedolizumab

(L04AB01) etanercept

etanercept

(L04AB02) infliximab

infliximab

(L04AB04) adalimumab

adalimumab

(L04AB05) certolizumab pegol

certolizumab pegol

(L04AB06) golimumab

golimumab

(L04AC03) anakinra

anakinra

(L04AC05) ustekinumab

ustekinumab

(L04AC07) tocilizumab

tocilizumab

(L04AC10) secukinumab

secukinumab

(L04AC12) brodalumab

brodalumab

(L04AC13) ixekizumab

ixekizumab

(L04AC14) sarilumab

sarilumab

(L04AC16) guselkumab

guselkumab

(L04AC17) tildrakizumab

tildrakizumab

(L04AC18) risankizumab

risankizumab

Population studied

Short description of the study population

Elderly patients using biological drugs in the Italian Valore distributed database (2010-2022)

Age groups

- Elderly (≥ 65 years)
 - Adults (65 to < 75 years)
 - Adults (75 to < 85 years)
 - Adults (85 years and over)
-

Special population of interest

Other

Special population of interest, other

Patients over 65 years

Estimated number of subjects

25000

Study design details

Setting

Italian setting

Comparators

None

Outcomes

Adherence, persistence of biological treatment

Data management

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), other

Italian VALORE distributed database

Data sources (types)

[Administrative healthcare records \(e.g., claims\)](#)

Use of a Common Data Model (CDM)

CDM mapping

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Unknown