Switch pattern of biological drugs (originator and biosimilars) for the treatment of chronic immune-mediated inflammatory diseases through an Italian network of regional administrative databases: the VALORE Project

First published: 14/12/2022

Last updated: 13/03/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/50140

EU PAS number

EUPAS50139

Study ID

50140

DARWIN EU® study

No

Study countries

☐ Italy

Study description

In September 2022 EMA stated that biosimilars are comparable to their reference products in terms of safety and immunogenicity and are therefore interchangeable. However, for a single active ingredient numerous biosimilars are marketed and switching patterns among biological drugs might be very various and complex. The aim of this study is to describe the pattern of switch and swap among incident users of biological drugs approved for IMIDs in dermatology, rheumatology, and gastroenterology. A retrospective cohort study will be conducted using the claims data of nine Italian regions from 2010 to 2020 (VALORE project). Incident users of biologic drug with an indication for IMIDs will be included. Characteristics of patients, pattern of switch and swap among biological drugs with related predictive factors will be described by therapeutic indication. We are confident to finalize the results of this study by the end of March 2023.

Study status

Finalised

Research institutions and networks

Institutions

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

Italy

First published: 25/10/2022

Last updated: 13/03/2025

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

Unit of adverse drug reactions monitoring (UADRM), University Hospital of Pisa

Italy

First published: 08/01/2014

Last updated: 16/02/2024

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

Centro Regionale di Farmacovigilanza (PhV Regional Centre of Lombardy, Italy), Regione Lombardia

Italy

First published: 09/02/2010

Last updated: 14/03/2018

Institution | Other | ENCePP partner

Department of Epidemiology of the Regional Health Service - Lazio

Italy

First published: 23/03/2010

Last updated: 22/06/2018

Institution | EU Institution/Body/Agency | ENCePP partner

Azienda Zero Veneto, Italy, Epidemiologic Observatory of the Sicily Regional Health Service Palermo, Sicilia, Italy, Territorial Assistance Service, Drug and Medical Device Area, Emilia Romagna Health Department Bologna, Emilia Romagna, italy, Azienda Regionale per l'Innovazione e gli Acquisti, S.p.A Milano, Lombardia, Italy, Apulian Regional Health Department Bari, Apulia, Italy, Unit of Adverse

Drug Reaction Monitoring, University Hospital of Pisa Pisa, Toscana, Italy, Direzione Centrale Salute Regione Friuli Venezia Giulia Trieste, Friuli Venezia Giulia, Italy, Azienda regionale di coordinamento per la salute (ARCS) Udine, Friuli Venezia Giulia, Italy, Hospital Pharmacy Unit, Trento General Hospital Trento, Autonomous Province of Trento, Italy, Azienda Provinciale per i Servizi Sanitari Trento, Autonomous Province of Trento, Italy

Networks

VALORE

Contact details

Study institution contact

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Study contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/01/2019

Actual: 12/12/2022

Study start date
Planned: 01/01/2019

Actual: 12/12/2022

Date of final study report
Planned: 31/03/2023

Actual: 12/12/2022

Sources of funding

- Other

More details on funding

Agenzia Italiana del Farmaco (AIFA)

Study protocol

221206_Valore_Switch_protocol.pdf(1.3 MB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the pattern of switch and swap among incident users of biological drugs approved for IMIDs in different therapeutic areas (dermatology,

rheumatology and gastroenterology).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, multicenter study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AB02) infliximab

infliximab

(L04AB01) etanercept

etanercept

(L04AB04) adalimumab

adalimumab

(L04AB05) certolizumab pegol

certolizumab pegol

(L04AB06) golimumab

golimumab

(L04AC03) anakinra

anakinra

(L04AC10) secukinumab

secukinumab

(L04AA24) abatacept

abatacept

(L04AG05) vedolizumab

vedolizumab

(L04AC05) ustekinumab

ustekinumab

Medical condition to be studied

Colitis ulcerative

Crohn's disease

Psoriasis

Rheumatoid arthritis

Psoriatic arthropathy

Additional medical condition(s)

Axial spondylarthritis

Population studied

Short description of the study population

The study population included incident users of biological drugs approved for the immune mediated inflammatory diseases (IMIDs) in dermatology, rheumatology, and gastroenterology identified through the regional claims databases from 2010 to 2020.

Age groups

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

30000

Study design details

Data analysis plan

Descriptive analyses will be conducted to assess demographic and clinical characteristics of biological drug users in relation to indication of use. Continuous variables will be described by means and standard deviation or by median and interquartile range (in case of outliers). Categorical variables will be described by patient counts and percentages. Starting from the index drug, we will describe switching to biosimilar or originator, swapping to other classes different from the index drug class or no switching by using proportions. Also the switch back and multiple switch will be described. Time to switch and swap will be described using a Kaplan Meier approach stratifying by indication and class of biological drugs.

Data management

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No