Identifying treatment discontinuation with biological drugs for immune-related inflammatory diseases using administrative healthcare data: a scoping review

First published: 14/06/2023

Last updated: 13/03/2025

Study Planned

Administrative details

EU PAS number

EUPAS105336

Study ID

105337

DARWIN EU® study

No

Study countries

Italy

Study description

Administrative/claims healthcare data have become an essential tool for studying the long-term use of biologic drugs in the real-world clinical practice. However, the major limitation of administrative/claims data is represented by the lack of clinical information, including the date and the reason for drug discontinuation. Nevertheless, this information can be derived using appropriate algorithms. In general, algorithms to identify discontinuation events using administrative/claims data should be designed by the investigator according to both the information on the utilization of the study drug that is recorded into the data source (e.g. days supplied, number of dosage units, strength) and the expected pattern of use of the drug of interest in the study population (e.g. one administration per month). The measurement of the duration of each drug utilization record whenever days supplied are not available, the length of the allowed gap between two consecutive drug utilization records, the possibility of stockpiling medications and the time-wise approach to identify the date of discontinuation requires specific investigator choices that can ultimately affect the levels of persistence observed in the study population. As with any medication used for chronic diseases, the monitoring of the long-term use is paramount to ensure patient safety and treatment effectiveness. With respect to biological drugs used for immune-mediated inflammatory diseases (IMIDs), monitoring of long-term persistence can indirectly provide valuable information about patients' satisfaction with treatment, safety, and effectiveness. Therefore, we aim at performing a scoping review of the published literature to describe and discuss the different approaches adopted to identify in administrative/claims data the discontinuation of biological drugs in patients affected by IMIDs.

Study status

Planned

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**

Networks

VALORE

Contact details

Study institution contact

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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: 01/01/2018

Study start date
Planned: 01/06/2023

Date of final study report
Planned: 29/09/2023

Sources of funding

- Other

More details on funding

Italian Medicine Agency (AIFA)

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:

Not applicable

Main study objective:

The objective of this scoping review is to describe and discuss the different approaches adopted in the published literature to identify in administrative/claims data the discontinuation of biological drugs in patients affected by IMIDs

Study drug and medical condition

Medicinal product name, other

Any biologic used for IMIDs

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

Medical condition to be studied

Fibromyalgia

Arthritis

Ankylosing spondylitis

Psoriasis

Additional medical condition(s)

Any immune-related inflammatory diseases (IMIDs)

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- 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

0

Study design details

Data analysis plan

Information extracted from included studies will be described accconcerned three main domains: the datasource characteristics (data source name, catchment area, healthcare setting of collection of drug utilization records), biological drug and population (substance name, indication/study cohort, study period), and the method applied for measuring discontinuation (measure of discontinuation frequency/probability, observed frequency/probability of discontinuation, follow-up duration, censoring criteria, unit of measurement of duration of a single drug utilization record e.g. DDD, grace period, stockpiling, identification of the discontinuation date, overall description of discontinuation-finding algorithm). The synthesis included quantitative analysis (e.g. frequency analysis) of the scoping review conduct (i.e. methodological steps) and qualitative analysis (i.e. content analysis) of the components of the research purpose, and conceptual definition of scoping reviews

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

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No