Persistence of AMGEVITA® in patients with plaque psoriasis: a retrospective database analysis from the British Association of Dermatology Biologics and Immunomodulators Register (20210149)

First published: 19/04/2022

Last updated: 08/08/2023

Study Finalised

Administrative details

EU PAS number

EUPAS46292

Study ID

47125

DARWIN EU® study

No

Study countries

- [ ] Ireland
- [ ] United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Amgen

United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 164 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.
medinfo@amgen.com

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 14/12/2018

Study start date
Actual: 14/12/2018

Data analysis start date
Actual: 14/01/2022

Date of final study report
Planned: 31/12/2022

Actual: 02/05/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20210149 01.02.06 Public Redacted Protocol Ver 1.0 English.pdf(1.34 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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The main objective of the study is to describe the persistence of Amgevita in plaque psoriasis patients according to prior adalimumab/biologic experience.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective database analysis

Study drug and medical condition

Name of medicine

AMGEVITA

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

Patients aged 18 years or older diagnosed with plaque psoriasis received Amgevita for the treatment and registered in the BADBIR registry for the period of October 2018 to July 2021.

Inclusion criteria:

- Diagnosed with plaque psoriasis

- Patients ≥18 years of age at Amgevita initiation (index date)
- Received at least one dose of Amgevita
- Observed at least 6 months of follow-up data after starting Amgevita

Exclusion criteria:

None

Age groups

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)

Special population of interest

Other

Special population of interest, other

Patients with plaque psoriasis

Estimated number of subjects

1598

Study design details

Outcomes

• Median (or mean) time to first Amgevita discontinuation (in months). • Cumulative probability of discontinuation at 6,12, and 24 months. • All outcomes will be described by the following categories of biologic exposure: o

Adalimumab/Biologic-naïve o Prior Adalimumab o Other Prior Biologic, Throughout study: Frequency & proportion of each reason given for discontinuing Amgevita Frequencies & proportions of all characteristics at baseline

Data analysis plan

Analyses of primary and secondary endpoints will be performed separately for biologic-naïve and biologic-experienced participants. Continuous variables will be described using the mean with standard deviation, median with interquartile range (IQR) and range, whereas categorical variables will be described using frequencies and proportions. Persistence will be assessed using Kaplan-Meier survival estimates and plots. The median durations and event probabilities at 6, 12, and 24 months after index date will be reported. Changes in PASI or DLQI scores will be derived by subtracting scores at 6, 12, and 24 months from baseline.

Documents

Study results

20210149 01.47.01.01 Observational Research Study Report Published Report_Redacted.pdf(284.32 KB)

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 source(s), other

British Association of Dermatology Biologics and Immunomodulators Registry (BADBIR) United Kingdom

Data sources (types)

Disease registry

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