Burden of Illness Among Patients with Gout and Treated with Pegloticase (20240302)

First published: 24/02/2025

Last updated: 21/04/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000475

Study ID

1000000475

DARWIN EU® study

No

Study countries

☐ United States

Study description

This retrospective cohort study will describe patient characteristics and treatment patterns and compare gout flares, laboratory measures, and HCRU and cost between the pre- and post-pegloticase initiation periods among gout

patients in a real-world setting using administrative claims data from the MORE2 Registry® and the 100% Medicare FFS database. The objective of the study are 1. To describe the patient characteristics of pegloticase initiators. 2. To examine the treatment patterns pre and post pegloticase initiation. 3. To assess gout- and flare-related healthcare resource utilization and costs pre- and post-pegloticase initiation.

Study status

Ongoing

Research institutions and networks

Institutions

Amgen

United States

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Institution

Inovalon (Vendor)

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
Planned: 22/08/2024

Actual: 22/08/2024

Study start date
Planned: 17/02/2025

Actual: 17/02/2025

Data analysis start date
Planned: 17/02/2025

Actual: 17/02/2025

Date of final study report
Planned: 31/12/2025

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

Protocol-Published Original pegloticase 20240302 .pdf(328.07 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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Study drug and medical condition

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

PEGLOTICASE

Anatomical Therapeutic Chemical (ATC) code

(M04AX02) pegloticase

pegloticase

Medical condition to be studied

Gout

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

Yes

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes