A real-world observational study of treatment patterns and outcomes for patients with neuromyelitis optica spectrum disorders (NMOSD) treated with inebilizumab (UPLIZNA) in Europe

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Study Planned

Administrative details

EU PAS number

EUPAS1000000084

Study ID

1000000084

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Germany

- [ ] Italy
- [ ] Netherlands
- [ ] Spain

Study description

The overall research questions for this study are: 1) What are the demographic, clinical, and treatment characteristics of a population of patients who initiate inebilizumab in real-world practice? 2) What are inebilizumab treatment patterns in the first 12 months following treatment initiation? 3) What is the incidence of adverse events of special interest (AESI) in the first 12 months following treatment initiation?

Specific objectives are:

• To describe demographic, clinical and treatment characteristics of patients at the time of first inebilizumab treatment

• To describe inebilizumab treatment patterns in the first 12 months following treatment initiation in terms of dosing, duration of treatment, frequency of drug discontinuation, switching, and use of add-on therapies

• To quantify the incidence of AESI, including serious infections, opportunistic infections, hepatitis B reactivations, serious infusion related reactions, and malignancies.

Analyses will be performed in the overall study population and in sub-groups of special interest: patients concomitantly receiving other immunosuppressive agents and patients aged >65 years at index date.

Study status

Planned

Research institutions and networks

Institutions

Global Database Studies, IQVIA

- [ ] Czechia
- [ ] Finland
- [ ] Germany
- [ ] Slovakia
- [ ] Spain

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Institution | Other | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ana Cristina Santos

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 17/08/2022

Actual: 17/08/2022

Study start date
Planned: 30/04/2024

Date of final study report
Planned: 31/12/2028

Sources of funding

- Pharmaceutical company and other private sector

Study protocol

HZNP-UPL-402 Protocol_v2.0_clean_17Feb2023_redacted.pdf (1.08 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study design:

A non-interventional multi-center cohort study of patients initiating inebilizumab conducted with secondary data sources in France, Germany, Italy, the Netherlands, and Spain.

Main study objective:

This study aims to characterize patients who initiate inebilizumab, describe treatment patterns and incidence of adverse events of special interest (AESI) in the first 12 months following treatment initiation.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

UPLIZNA

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

INEBILIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AA47) inebilizumab

inebilizumab

(L04AG10) inebilizumab

inebilizumab

Medical condition to be studied

Neuromyelitis optica spectrum disorder

Population studied

Short description of the study population

The study population will be identified in national healthcare administrative databases, claim databases and disease-specific registries and will include adult (18 years old or more at the index date) female and male patients diagnosed with NMOSD and initiating inebilizumab during the study period.

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

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)

Système National des Données de Santé (French national health system main database)

PHARMO Data Network

The Information System for Research in Primary Care (SIDIAP)

Data source(s), other

Observatoire Français de la Sclérose en Plaques (OFSEP)

Gesetzliche Krankenversicherung (GKV)

Registro Italiano Sclerosi Multipla e Patologie Correlate (RISM)

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

Unknown