Observational Post-Authorisation Study of Oxervate® (Cenegermin 20 µg/ml) eye drops in the treatment of adult patients with moderate or severe Neurotrophic Keratopathy. (DEV0118)

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Study Finalised

Administrative details

EU PAS number

EUPAS32335

Study ID

45907

DARWIN EU® study

No

Study countries

Italy

Study description

Oxervate® was approved for the treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratopathy in adults by European Medicines Agency in 2017. The objective of this study is to describe treatment patterns for adult patients receiving Oxervate® for the cure of moderate or severe Neurotrophic Keratopathy to give insight on the utilization of this topical treatment in real-world clinical practice rather than strict conditions imposed by a formal clinical trial. This long-term product registry aims to consolidate existing data sources on patients diagnosed with moderate or severe Neurotrophic Keratopathy exposed to Oxervate® in qualified ophthalmological centers from participating countries in EU.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 7 centres are involved in the study

Contact details

Study institution contact

Flavio Mantelli flavio.mantelli@dompe.com

Study contact

flavio.mantelli@dompe.com

Primary lead investigator

Alessandro Lambiase

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/09/2018

Study start date

Actual: 17/06/2019

Date of final study report

Planned: 31/12/2021

Actual: 06/09/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Dompé farmaceutici S.p.A.

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:

Other

If ‘other’, further details on the scope of the study

Real World Evidence

Data collection methods:

Primary data collection

Main study objective:

The main objective of this observational study is to describe treatment patterns for adult patients receiving Oxervate® for the cure of moderate and severe Neurotrophic Keratopathy to give insight on the utilization of this topical treatment in real-world clinical practice rather than strict conditions imposed by a formal clinical trial.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicentre, prospective, observational study/registry, Post-Authorisation Study

Study drug and medical condition

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

CENEGERMIN

Medical condition to be studied

Neurotrophic keratopathy

Population studied

Short description of the study population

Adult patients diagnosed with moderate or severe NK were planned to be enrolled at approximately 30 sites in selected European countries (Italy,

Germany, Spain,
France).

Inclusion criteria
The following were the requirements for entry into the study:
1. Male or female 18 years of age or older.
2. Diagnosis of moderate (persistent epithelial defect, PED) or severe (corneal ulcer) neurotrophic keratopathy by the Investigator.
3. The prescribing decision has been made to initiate treatment with Oxervate®.
4. Written documentation of informed consent has been obtained in accordance with the relevant Country and local privacy requirements, as applicable.

Exclusion criteria
The following were the criteria for exclusion from participating in the study:
1. Patients who were contraindicated to Oxervate® treatment as per the European SmPC.
2. Concurrent participation in a clinical trial that dictated treatment or use of an investigational drug

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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

Neurotrophic keratopathy patients

Estimated number of subjects

250

Study design details

Outcomes

The objective of this study is to describe treatment patterns for adult patients receiving Oxervate® for the cure of moderate or severe Neurotrophic Keratopathy (NK).

Data analysis plan

Summary descriptive statistics and rate calculation will be presented analyzing demographic data on patients (age, sex, ethnicity, race), prior disease data (disease course time of disease onset, date of diagnosis, symptoms at onset, past disease activity and stage), referral flow (patient from general practitioner/ophthalmologist, other hospital, other private clinic, Investigator, Emergency Room of the same center), treatment data (symptomatic therapies, previous and current therapies including Oxervate®, other therapies for other conditions), relevant clinical tests and clinical events of medical interest. The safety population which includes any patient who receives at least one treatment of Oxervate® regardless of the length of follow-up. Treatment exposure will be summarized in terms of compliance to treatment.

Documents

Study results

DEV0118 Clinical Research Report Final Version 1.0_06092021.pdf (1.74 MB)

Data management

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)

Other

Data sources (types), other

Prospective patient-based data collection

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