Documentation of the use of Varitect® CP in patients with herpes zoster, the VARIZOSTA study (NIS-022)

First published: 16/02/2023

Last updated: 06/03/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS103611

Study ID

105651

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Assessment of the real-world usage of Varitect CP in patients with HZ. HZ patients, both treated with and without Varitect CP, will be documented in the NIS. Non-interventional, prospective, controlled, multi-center, post-approval study.

Study status

Ongoing

Research institutions and networks

Institutions

Universitätsklinikum Schleswig-Holstein

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Institution

Klinik für Dermatologie,Allergologie und Venerologie

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Terheyden

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/09/2022

Study start date

Planned: 31/03/2023

Actual: 01/06/2023

Data analysis start date

Planned: 30/06/2026

Date of final study report

Planned: 31/03/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biotest AG

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 type:

Non-interventional study

Scope of the study:

Disease epidemiology

Main study objective:

Assessment of the real-world usage of Varitect CP in patients with HZ. HZ patients, both treated with and without Varitect CP, will be documented in the NIS.

Population studied

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)

Estimated number of subjects

160

Study design details

Data analysis plan

All analyses will be exploratory. Since there are no confirmatory analyses planned, hypotheses are not formulated. Data will be analyzed using descriptive statistics. A statistical analysis plan will be prepared.

Data management

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