Non-interventional long term study (NIS) for the clinical usage of Biotest IVIGs in various indications (Biotest NIS-020)

First published: 10/06/2021

Last updated: 23/04/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/41517

EU PAS number

EUPAS41516

Study ID

41517

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The experience gained with immunoglobulin preparations (IVIGs) during the approval phase is limited. Implementation of this post-authorization study serves to check the tolerance profile, effectiveness and patient satisfaction during use in the medical routine in various indications.

Study status

Ongoing

Research institutions and networks

Institutions

Biotest

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Stephan Borte

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 26/10/2020

Study start date
Actual: 01/06/2021

Data analysis start date
Planned: 02/06/2025

Date of final study report
Planned: 30/12/2025

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:

The aim of the study is to gain knowledge about the efficacy and patient satisfaction. Further study objectives are an additional gain in knowledge about tolerance and safety by broadening the database under everyday conditions.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Sentinel sites

Study drug and medical condition

Medical condition to be studied

Neuropathy peripheral

Myasthenia gravis

Primary immunodeficiency syndrome

Secondary immunodeficiency

Population studied

Age groups

Adolescents (12 to < 18 years)

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

3000

Study design details

Data analysis plan

The statistical evaluations are carried out using the SAS program. The quantitative variables are described by number of values, mean, median, standard deviation, where appropriate, confidence interval, minimum and maximum. The qualitative variables are represented with the help of absolute (n) and relative (%) frequencies.

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