Immunoglobulin substitution for infection prevention and treatment of primary and secondary immune deficiency syndromes (German title: Immunoglobulinsubstitution zur Infektionsprävention und Behandlung bei primären und sekundären Immunmangelsyndromen) (NIS Intratect 50g/l)

First published: 18/11/2014

Last updated: 06/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7969

Study ID

27431

DARWIN EU® study

No

Study countries

Germany

Study description

Rationale and background: The experience with immunoglobulins (IVIGs) obtained in clinical trials for registration is limited. The current non-interventional study is conducted to confirm the safety and effectiveness of the IVIG Intratect (50 g/l) with real life data from daily practice. Study design: Non-interventional, national, multicenter, prospective, observational study

Study status

Finalised

Research institutions and networks

Institutions

Biotest

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 115 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Barbara Tschechne

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 01/04/2011

Study start date

Actual: 01/04/2011

Data analysis start date

Planned: 02/01/2022

Actual: 01/10/2021

Date of final study report

Planned: 30/06/2022

Actual: 27/09/2022

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Primäres Studienziel ist ein zusätzlicher Erkenntnisgewinn zur Verträglichkeit und Effektivität durch Verbreiterung der Datenbasis unter Alltagsbedingungen

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

National, multicenter, prospective, observational study

Study drug and medical condition

Medicinal product name, other

Intratect

Medical condition to be studied

Primary immunodeficiency syndrome

Secondary immunodeficiency

Population studied

Short description of the study population

Patients with primary and secondary immune deficiency syndromes receiving treatment with immunoglobulins (IVIGs).

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

Immunocompromised

Estimated number of subjects

2.500

Study design details

Data analysis plan

Verträglichkeit: Unerwünschte Ereignisse (UE) mit Kausalitätsbewertung durch den Prüfarzt und Dokumentation des Zeitpunkts nach Beginn der Infusion. Kategorisiert nach Zeitlich Assoziierten Unerwünschten Ereignissen (ZAUE = alle UE <72 h nach Beginn der Infusion) Wirksamkeit stratifiziert nach Indikation und Vorbehandlung: (1) Primärem Immunglobulinmangel (2) Sekundärem Immunglobulinmangel (3) IVIG-vorbehandelt oder nicht vorbehandelt

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)

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