Non-interventional prospective safety study as part of the routine pharmacovigilance in patients treated with Intratect 100 g / l (German title: Nicht-interventionelle prospektive Unbedenklichkeitsstudie im Rahmen der Routine-Pharmakovigilanz bei Intratect 100 g/l behandelten Patienten) (NIS Intratect 100 g/l)

First published: 25/11/2014

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8040

Study ID

27175

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The primary objective of the study is to gain additional insights on tolerance by broadening the database under real life conditions. Secondary objectives are to broaden the of knowledge on the effectiveness and to identify patients at risk due to pre-existing illnesses and risk factors

Study status

Finalised

Research institutions and networks

Institutions

Biotest

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 47 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Rainer Schmeidl

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/01/2013

Study start date

Actual: 01/03/2013

Data analysis start date

Actual: 01/10/2021

Date of interim report, if expected

Planned: 30/06/2019

Date of final study report

Planned: 30/06/2022

Actual: 22/08/2022

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

Other study registration identification numbers and links

Biotest NIS-011

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

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is to gain additional insights on tolerance by broadening the database under real life conditions

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Intratect 100 g/l

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 received treatment with intratect (100 g/l).

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

1000

Study design details

Outcomes

Adverse events dependent on relatedness and seriousness, Effectiveness, identification of patients at risk due to pre-existing illnesses and risk factors

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Data analysis plan

Descriptive statistics

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