

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

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**Study ID**

27175

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**DARWIN EU® study**

No

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### Study countries

Germany

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### 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

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### 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

Artur Bauhofer [artur.bauhofer@biotest.com](mailto:artur.bauhofer@biotest.com)

Study contact

[artur.bauhofer@biotest.com](mailto:artur.bauhofer@biotest.com)

### Primary lead investigator

Rainer Schmeidl

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 28/01/2013

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### Study start date

Actual: 01/03/2013

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### Data analysis start date

Actual: 01/10/2021

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### Date of interim report, if expected

Planned: 30/06/2019

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### 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

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### **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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

**Data collection methods:**

Primary data collection

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**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

**Medicinal product name, other**

Intratect 100 g/l

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**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).

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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)
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### **Special population of interest**

Immunocompromised

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### **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

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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No