

# Non-interventional safety study on the tolerability and safety of octagam® 5%, octagam® 10% or panzyga®

**First published:** 16/10/2014

**Last updated:** 03/05/2022

Study

Finalised

## Administrative details

### EU PAS number

EUPAS7687

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### Study ID

46952

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### DARWIN EU® study

No

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### Study countries

 Germany

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### Study status

Finalised

## Research institutions and networks

## Institutions

### Octapharma

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 200 centres are involved in the study

## Contact details

### Study institution contact

Carolin Asseburg [carolin.asseburg@octapharma.com](mailto:carolin.asseburg@octapharma.com)

Study contact

[carolin.asseburg@octapharma.com](mailto:carolin.asseburg@octapharma.com)

### Primary lead investigator

Semi Tascou

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2014

Actual: 01/01/2014

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**Study start date**

Planned: 01/01/2014

Actual: 07/03/2014

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**Date of final study report**

Planned: 31/12/2021

Actual: 24/01/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Octapharma GmbH

## 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

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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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

Drug utilisation

Other

**If 'other', further details on the scope of the study**

Health related quality of life

**Data collection methods:**

Primary data collection

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**Main study objective:**

The main objective of the study is the evaluation of data on tolerability and safety of octagam® 5%, octagam® 10% and panzyga® in all labelled indications.

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Non-interventional post-authorisation safety study

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(J06BA02) immunoglobulins, normal human, for intravascular adm.  
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## **Medical condition to be studied**

Secondary immunodeficiency  
Immunomodulatory therapy  
Primary immunodeficiency syndrome

## **Population studied**

### **Short description of the study population**

It was planned to document the treatment of 5,000 patients. Patients of both genders and all ages who receive octagam® 5%, octagam® 10% or panzyga® for replacement therapy or immunomodulation as recommended by the corresponding SmPC could be enrolled. There were no additional formal inclusion or exclusion criteria defined.

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### **Age groups**

- Preterm newborn infants (0 - 27 days)
- Term newborn infants (0 - 27 days)
- Infants and toddlers (28 days - 23 months)
- Children (2 to < 12 years)
- 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)
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### **Estimated number of subjects**

5000

## Study design details

### **Outcomes**

The primary outcome is the number and the type of reported adverse drug reactions. Quality of life will be evaluated by using the SF-36 health Survey. Effectiveness by utilising laboratory data.

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### **Data analysis plan**

Treatment with octagam® 5%, octagam® 10% and panzyga® is documented. This includes data about the patient's disease, age, gender, weight, concomitant medication or illness. For each application, the date and duration of infusion, dose, batch number(s) and the absence or occurrence of an adverse drug reaction (ADR) is recorded. In case of an ADR, additional detailed information about the reaction is recorded. If available, laboratory data about the efficacy of treatment should also be documented.

## Documents

### **Study results**

[GAM-33\\_summary\\_results.pdf](#) (253.03 KB)

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## 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