# Study on the use of non-specific immunoglobulins in patients treated at Vall d'Hebron University Hospital, Bellvitge Hospital and Germans Trias i Pujol Hospital, collected in the CatSalut's patient and treatment registry (RPT). (VDH-IGG-2021-03)

**First published:** 08/09/2022

**Last updated:** 23/04/2024

Study | Ongoing

## Administrative details

**EU PAS number**

EUPAS48635

**Study ID**

48636

**DARWIN EU® study**

No

**Study countries**

Spain

**Study description**

A retrospective, multicenter, observational drug study (EOM) of diseases treated with nonspecific immunoglobulins in the clinical services of the Vall d'Hebron (HUVH), Bellvitge (HUB) and Germans Trias i Pujol (HUGTiP) hospitals. The main objectives are to describe the use of non-specific immunoglobulins in the aforementioned hospitals and to evaluate in which indications they are being administered from the RPT and to validate the indications for use of non-specific immunoglobulins from the RPT of HUVH, HUB and HGTiP.

**Study status**

Ongoing

# Research institutions and networks

## Institutions

### University Hospital Vall d’Hebron (HUVH)

Spain

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

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

**Institution** | **Educational Institution** | **Hospital/Clinic/Other health care facility**

## Clinical Pharmacology Service, Bellvitge University Hospital/IDIBELL

Spain

**First published:** 30/04/2010

**Last updated:** 20/08/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

## Clinical Pharmacology, Vall d'Hebron Institut de Recerca (VHIR)

Spain

**First published:** 18/05/2021

**Last updated:** 20/05/2021

Institution | Outdated | Hospital/Clinic/Other health care facility | ENCePP partner

## Hospital Germans Trias i Pujol. Barcelona

# Contact details

**Study institution contact**

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Study contact

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**Primary lead investigator**

Judit Riera Arnau

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 01/01/2022

Actual: 01/01/2022

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**Study start date**

Planned: 01/02/2022

Actual: 01/02/2022

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**Data analysis start date**

Planned: 01/05/2022

Actual: 01/06/2022

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**Date of interim report, if expected**

Planned: 26/06/2022

Actual: 26/06/2022

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**Date of final study report**

Planned: 01/02/2023

## Sources of funding

- Other

## More details on funding

Independent study with no funding

## 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 type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Main study objective:**

Overall objective: - To describe the use of immunoglobulins in HUVH, HUB and HGTiP. - To validate the indications for the use of immunoglobulins in the RPT of

three third level hospitals belonging to Catsalut.

## Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**

(J06BA) Immunoglobulins, normal human

Immunoglobulins, normal human

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**Medical condition to be studied**

Dermatomyositis

Guillain-Barre syndrome

Myasthenic syndrome

Myasthenia gravis

Chronic inflammatory demyelinating polyradiculoneuropathy

Multifocal motor neuropathy

Stiff person syndrome

Pancytopenia

Systemic lupus erythematosus

Kawasaki's disease

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**Additional medical condition(s)**

Erythrocyte aplasia associated to parvovirus B19, hypogammaglobulinemia secondary to myeloma and chronic lymphocytic leukemia, and post-bone marrow transplantation. Primary and secondary antibody deficiency, including transplant patients, toxic shock syndrome, necrotizing fasciitis, prophylaxis for varicella zoster virus, vasculitis, pemphigoid, toxic epidermal necrolysis and bullous diseases.

## Population studied

**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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**Special population of interest**

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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**Estimated number of subjects**

500

# Study design details

**Outcomes**

Use of immunoglobulins and level of evidence for indications (authorized, not authorized with scientific evidence, not authorized and not accepted).

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**Data analysis plan**

Standard descriptive calculations for qualitative and quantitative variables will be used. The median of general characteristics and treatment duration will be calculated. The gender distribution is also mapped out. The calculations are made with the patients who switch. The number of switches, the mean time between switching and the number of switches per patient are mapped out. The proportion of patients for each indication will be calculated as well as the proportion of patients in each group. Information will also be calculated by person-month. For the RPT validation of the diagnosis the information recorded in the electronic health record, SAP of the participating hospitals, will be used as “gold standard”. The positive predictive value is used for validation of the RPT. To make sure the validation is reliable the Cohen's kappa score and percent agreement will be calculated. Results will be stratified by age, sex, IgG, level of evidence and center.

# 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)**

Administrative healthcare records (e.g., claims)

Other

**Data sources (types), other**

Exposure registry

# 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

# Procedures

# Procedure of results generation

## Statistical Analysis Plan

English (366.92 KB - PDF)

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