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 | 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

Study start date

Planned: 01/02/2022

Actual: 01/02/2022

Data analysis start date

Planned: 01/05/2022

Actual: 01/06/2022

Date of interim report, if expected

Planned: 26/06/2022

Actual: 26/06/2022

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

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

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

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)

Special population of interest

Renal impaired

Hepatic impaired

Immunocompromised

Pregnant women

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).

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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