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

PURI
https://redirect.ema.europa.eu/resource/48636

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 institution 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
25/06/2020

Institution
Educational Institution
Hospital/Clinic/Other health care facility
ENCePP partner

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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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

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

Data sources

Data sources (types)
Administrative data (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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