

DEVELOPMENT OF A PRIORITISATION PROTOCOL FOR THE USE OF IMMUNOGLOBULINS IN VIEW OF THE GLOBAL SUPPLY PROBLEM

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BACKGROUND AND IMPORTANCE

Highly purified IgG (95%) are obtained from the purification of human plasma extracted from healthy donors. The mechanism of action consists of an **antigen-specific activity**, exerting **immunomodulatory** functions in addition to those of the natural immunoglobulins. The increase in its **demand**, the dependence exclusively on **plasma donations** and the **pandemic** situation have reduced the supply of immunoglobulins worldwide.

OBJECTIVE

To elaborate a protocol at regional level (7 hospitals) to prioritize, rationalize and reduce the use of immunoglobulins in view of the worldwide supply problem.

MATERIAL AND METHODS:

• **Design:** A multidisciplinary work-team was created made up of professionals involved in the use of these therapies (immunologists, hematologists, internists, neurologists, pediatricians and pharmacists).

The **main pathologies** involved were specified.

Indications depicted in the **technical data** sheet and the **available scientific** evidence were reviewed, to define three priority groups:

1. **PRIORITY 1:** Necessary treatment, there is no other therapeutic alternative.
2. **PRIORITY 2:** Pathologies or clinical situations where the use of immunoglobulins is recommended.
3. **PRIORITY 3:** Clinical situations without sufficient scientific evidence.

Finally, the **indications** and **dose regimen** of all patients under active treatment were reviewed.



RESULTS:

PRIORITY 1	
Chronic treatments	<ul style="list-style-type: none"> - Primary and secondary immunodeficiencies - CAR-T hypogammaglobulinemia in pediatrics - Pure motor Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) - Multifocal motor neuropathy
Acute treatments	<ul style="list-style-type: none"> - Kawasaki-disease - Primary Immune Thrombocytopenia (PIT) before undergoing urgent surgery - PIT with severe thrombopenia/large bleeding diathesis
PRIORITY 2	
	<ul style="list-style-type: none"> - Guillain-Barre síndrome - Myasthenia-gravis - PIT with high risk of bleeding - CIDP (excluding pure motor) - Severe neonatal sepsis - Alloimmune hemolytic disease in neonates - Alloimmune neonatal thrombocytopenia - Hemophagocytic syndrome - Pediatric multisystem inflammatory syndrome due to SARS-CoV-2



Pathologies not mentioned are considered **PRIORITY 3**, being evaluated by a **Multidisciplinary Experts Committee**.

- After reviewing the active treatments, **21%** of them were **temporarily suspended**.
- Since the protocol approval, **8 new cases** have been assessed as priority 3, being only **one of them denied**.



CONCLUSION:

-The creation of the **protocol** has made possible to **rationalize** the use of immunoglobulins, reducing their consumption and promoting the use of therapeutic alternatives. Thus, completely necessary treatments are guaranteed, through equitable and equal access throughout the region.