

# COMPARISON THE DIFFERENT INCLUSION AND EXCLUSION CRITERIA FOR TREATMENT WITH ECULIZUMAB IN SPAIN

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## OBJECTIVES

Paroxysmal nocturnal hemoglobinuria (PNH) causes by intravascular hemolysis, due to the absence of a protein in red blood cells which prevents destruction by complement. The eculizumab is a recombinant humanized monoclonal antibody, which purpose is to avoid hemolysis complement-induced.

Review of protocols and compare with the patients treated with eculizumab in our hospital.

## MATERIALS AND METHODS

Analyze the inclusion and exclusion criteria for treatment with eculizumab in four Autonomous Communities of Spain (Andalusia, Canary Islands, Catalonia and the Basque Country).

Compare the patients in our hospital with different criteria.

## RESULTS AND DISCUSSION

Among the inclusion criteria are important differences: the value of lactate dehydrogenase (LDH) as an indicator of intravascular hemolysis, must be higher than 1.5 the upper limit of normal (ULN) in the Basque Country and the Canary Islands. While the other communities must be more than  $LDH > 3 \text{ ULN}$ . One patient of our hospital did not exceed the value of  $LDH > 3 \text{ ULN}$  at the onset of the treatment. The first two also agree that patients should have a history of transfusion due to hemolytic anemia. While in Andalusia the patient should have received at least 4 transfusions in the past 12 months and in Catalonia than 8 transfusions in the same period. On the other hand, in Andalusia and Catalonia stand out as exclusion criteria myelodysplastic syndrome and marrow aplasia. The rest of communities excluded those with severe bone marrow failure expressed as platelet ( $< 30 \times 10^9$ ) and neutrophils ( $< 500/\text{mm}^3$ ). Currently, we have a patient with PNH and marrow aplasia.

INCLUSION CRITERIA				
	CANARY ISLANDS	BASQUE COUNTRY	ANDALUSIA	CATALONIA
Value of LDH	$> 1.5 \text{ ULN}$	$> 1.5 \text{ ULN}$	$> 3 \text{ ULN}$	$> 3 \text{ ULN}$
Transfusion due to hemolytic anemia	YES	YES	$\geq 4$ transfusions in the past 12 months	$\geq 8$ transfusions in the past 12 months
EXCLUSION CRITERIA				
Myelodysplastic syndrome and marrow aplasia	Platelet ( $< 30 \times 10^9$ ) and neutrophils ( $< 500/\text{mm}^3$ )	Platelet ( $< 30 \times 10^9$ ) and neutrophils ( $< 500/\text{mm}^3$ )	YES	YES

## CONCLUSIONS

There is a lack of consensus among the communities in the use of eculizumab which it with the different criteria. This causes that the same patient may or may not receive treatment depending on where they go to treat him.