

Drug Delivery & Formulation

Dosing Algorithm for Inhibitors of Complement-Mediated Activity

Brief Description of Technology

A validated algorithm to calculate when the next dose of an inhibitor of complement-mediated (C5) activity is required.

TECHNOLOGY ID

2015-0303

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Technology Overview

Inhibition of terminal complement-mediated activation has been shown to be an effective treatment for several diseases. However, the dosing has not been well standardized and clearance rates may be different in every patient based on disease type and activity. Investigators at Cincinnati Children's performed a study in pediatric hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA) patients to identify an optimal eculizumab dosing strategy. The pilot study revealed that a calculation using blood level of the soluble terminal complement complex (sC5b-9) and the patient's body weight accurately determined the eculizumab clearance rate in each patient based on TMA activity, thereby providing clinicians with the necessary information to determine when the next dose should be administered. In addition, the investigators found that inhibitors of terminal complement-mediated activation were given too infrequently without this algorithm.

Applications

Dosing for any inhibition of complement-mediated activation, including but not limited to: Paroxysmal Nocturnal Hemoglobinuria, Atypical Hemolytic Uremic Syndrome, HSCT-TMA, Ophthalmologic diseases, and Kidney diseases.

Advantages

- Confidence that patients sustain adequate complement system blockade
- Personalized treatment schedule tailored to the individual disease features

Market Overview

HSCT-TMA occurs in 25% to 35% of HSCT recipients. A study found that the size of phase I trials could be reduced by 20%-50% utilizing pharmacokinetically guided dose escalation.

Investigator Overview

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