

To measure confounding, an E-value is calculated for the primary endpoint (time-to-first adjudicated on-trial relapse).

Given the serious impact of NMOSD attacks, eculizumab approval precluded the use of a concurrent comparator for ethical reasons, as it would require assigning patients to placebo when effective treatments exist. A non-inferiority efficacy trial was also considered but recruiting the very large sample size to adequately power the study was not feasible for this ultra-rare disease. Thus, a standard randomized clinical trial design was used. The trial enrolled 58 adults with EDSS score = 7 to receive an infusion of ravulizumab every 8 weeks after the loading dose. The primary treatment period will end when the last enrolled patient reaches week 50 unless a predefined number of patients have an adjudicated on-trial relapse by that time. The entire treatment period will last up to ~4.5 years.

Conclusions

ALXN1210-NMO-307 is an ongoing study evaluating the efficacy and safety of ravulizumab in patients with AQP4+ NMOSD. It is designed to be consistent with PREVENT, and robust statistical methods will address the potential impact of an external comparator.

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Disease Characteristics of Seropositive Neuromyelitis Optica Spectrum Disorder in a Turkish Cohort

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Objective

To determine the clinical, demographic and imaging characteristics of a Turkish cohort with aquaporin-4-antibody positive (AQP4-IgG+) neuromyelitis optica spectrum disorder (NMOSD) from a single center.

Background

NA.

Design/Methods

35 patients seen between January-2008 and December-2020 with a diagnosis of AQP4-IgG+NMOSD who could be studied in detail were included in the study. Inclusion criteria for patients with NMOSD diagnosis was defined according to International Consensus Diagnostic Criteria (Wingerchuk et al.2015) and all patients were confirmed for AQP4-IgG positive serology at least once by Euroimmune transfected cells assay (EU90). Demographic, clinical and MRI data were obtained retrospectively.

Results

The female-to-male ratio was 16.5: 1. The mean age of disease onset was 26,16±10,96 years for patients with optic neuritis onset (n:12), and 43.17±11,95 for the subgroup that started with transverse myelitis (TM) (n:16), confirming a significant difference of age at onset according to the first attack type (p < 0.001). The mean age at onset in 5 patients with area postrema syndrome was 35,74±16,83. Half of the total attacks occurred within the first year of disease onset (98/196). The mean time to diagnosis was 2,98±5,78 years after the initial attack. Disease duration was 10,06±9,76 years. Cerebrospinal fluid oligoclonal bands were studied in 24 and were positive in 25%. An autoimmune rheumatologic disease comorbidity was present in 34.5% of the patients. In patients with MRI disclosing = 2 McDonald dissemination in space criteria (spinal included) was more common in TM group and correlated with a higher disability (EDSS) score.

Conclusions

Turkish AQP4-IgG+NMOSD patients whose disease start with optic neuritis have an earlier age of onset compared to the ones with TM onset. Half of the total attacks occur within the first year of disease onset. Patients with = 2 McDonald MRI dissemination in space criteria were more common in the TM group and had a higher disability (EDSS) score.

Disclosure: Samet Cam has nothing to disclose. Bade Gulec has nothing to disclose. Dr. Tutuncu has nothing to disclose. Sabahattin Saip has nothing to disclose. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for Novartis. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for Roche. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for Sanofi-Genzyme. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving as a Consultant for Biogen - TR. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Roche. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Abdi Ibrahim Ilac - TR. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Biogen - TR. Dr. Siva has received personal compensation in the range of \$500-\$4,999 for serving on a Scientific Advisory or Data Safety Monitoring board for Merck Serono. The institution of Dr. Siva has received research support from Turkish MS Society. The institution of Dr. Siva has received research support from The Scientific and Technological Research Council Of Turkey - Health Sciences Research Grants. Dr. Uygunoglu has nothing to disclose.

Nipocalimab's Selective Targeting of FcRn and IgG Clearance Preserves Key Immune Functions

Leona Ling, Steven Tyler, Christopher Beneduce, Faye Yu, Julia Brown, Sujatha Kumar, Rui Xu, Jay Duffner, William Avery

Objective

To characterize the effect of nipocalimab, a fully human, effectorless IgG1 anti-neonatal Fc receptor (FcRn) monoclonal antibody on immune function.

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