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Numbers Needed to Treat and Costs Per Improved Outcome Among Treatments for Myasthenia Gravis

Tom Hughes, Cynthia Qi, Jessie Wang, Hongbo Yang, Deborah Gelinas, Edward Brauer, Mandy Du, Rochelle Sun, Glenn Phillips

Objective

Assess number needed to treat (NNT) and costs required to achieve improvements in symptoms and functional activities with targeted therapies for myasthenia gravis (MG).

Background

NNT and cost per improved efficacy can help inform comparative clinical efficacy and cost-effectiveness across MG treatments.

Design/Methods

Relative to conventional therapy (CT), NNTs and annual costs for achieving one point improvement in Quantitative Myasthenia Gravis score (QMG), one additional patient with minimal clinically important difference (MCID) in QMG (i.e., = 3 points improvement), and one additional patient achieving minimal symptom expression (MSE; Myasthenia Gravis-

Activities of Daily Living score of 0 or 1) were estimated for efgartigimod (EFG), intravenous immunoglobulin (IVIg), and eculizumab (ECU). All treatments were used in conjunction with CT. Costs per improved outcome (CPR) were compared between EFG, IVIg, and ECU. Efficacy evaluated at week 4 of respective phase 3 randomized trials (ADAPT [NCT03669588], NCT02473952, REGAIN [NCT01997229]. Annual drug acquisition and administration costs (2021 USD) were considered.

Results

Compared with CT, mean NNTs to achieve one point improvement and MCID in QMG were 0.19 and 2.03 for EFG, 0.52 and 7.14 for IVIg, and 0.56 and 6.25 for ECU. NNTs to achieve an additional patient with MSE was 3.46 for EFG and 8.13 for ECU. Compared to EFG, the mean annual CPR to achieve one point improvement and MCID in QMG were higher for IVIg (Difference [95% confidence interval] = $36,130 [$14,024, $58,237] per point improvement in QMG; $661,561 [$0, $1,546,275] per one patient with MCID in QMG) and ECU ($340,659 [$158,038, $523,280]; $3,838,718 [$1,470,740, $6,206,695]). Cost to achieve one additional patient with MSE was $4,761,649 [$2,859,671, $6,663,626] higher for ECU compared with EFG.

Conclusions

Evidence indicates more favorable treatment benefit and economic value for EFG with fewer NNT and lower cost required to achieve improved outcomes compared to other treatments.

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The ExTINGUISH Trial: A Phase-2B Randomized Placebo-Controlled Trial of Inebilizumab in Anti-NMDA Receptor Encephalitis

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Objective

To assess the safety and efficacy of inebilizumab in patients with anti-N-methyl-D-aspartate receptor (NMDAR) encephalitis.

Background

The lack of approved therapies for NMDAR encephalitis has led to substantial variability in treatment. High-quality data is needed to guide treatment and optimize long-term outcomes in recovering patients. Inebilizumab is a humanized anti-CD19 monoclonal antibody that can be administered intravenously with good CSF penetration and high target engagement. Inebilizumab may be an efficacious treatment for NMDAR encephalitis, with the potential to achieve early robust and sustained suppression of NMDAR autoantibodies and CD19+ plasmablasts and plasma cells leading to better long-term outcomes.

Design/Methods

The ExTINGUISH trial is a Phase 2B randomized double-blind placebo-controlled trial designed to evaluate the safety and efficacy of inebilizumab 300 mg for the acute treatment of moderate-to-severe NMDAR encephalitis. 120 participants will be enrolled at 20 US and two European sites (Barcelona, Spain; Rotterdam, The Netherlands). All patients will receive standard "first-line" immunotherapies prior to randomization. Cyclophosphamide IV rescue therapy will be provided after 6 weeks to patients who fail to respond to initial treatment. Motor, cognitive, and functional outcomes will be assessed over 96 weeks. Study operations will be supported via the NINDS-supported NeuroNEXT infrastructure.

Results

Primary outcomes will be ascertained at 16 weeks using the change in modified Rankin scale (adjusted for rescue therapy) and accepted safety measures. Comprehensive neuropsychological tests, bedside cognitive screening tools, and quality of life/ functional indices will be measured across study participation (secondary outcomes). Clinical data will be combined with biofluid biomarkers of immune activation to inform the biologic contributors to outcomes and identify surrogate endpoints that may be used in future clinical trials (tertiary outcomes).

Conclusions

ExTINGUISH Trial findings will immediately influence patient care, while informing the design and implementation of future clinical trials in autoimmune encephalitis.

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