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## Examining Inebilizumab in Generalized Myasthenia Gravis: Insights from MINT

### Ryan Quigley:

You're listening to *Neurofrontiers* on ReachMD, and this is an *Audio Abstract*. I'm Ryan Quigley, and today, we'll be reviewing the MINT trial, which evaluated the efficacy and safety of inebilizumab in patients with generalized myasthenia gravis, or gMG.

For decades, gMG has tested the limits of immunosuppressive therapy. And while steroids, immunosuppressants, and newer biologics have improved outcomes, patients and clinicians still struggle with incomplete responses, treatment fatigue, and side-effect burdens. To address these challenges, the MINT trial—which was published in *The New England Journal of Medicine* in June 2025—introduces inebilizumab, a CD19-directed monoclonal antibody that serves as a novel contender in the gMG treatment landscape.

Before we discuss the study, it's important to know a little bit about inebilizumab. This therapy is designed to target CD19-positive B cells, including plasmablasts and plasma cells that pump out the autoantibodies fueling gMG. And unlike therapies focused on CD20, which B cells lose as they mature, CD19 lingers on these autoantibody-producing cells. That simple difference in molecular targeting makes inebilizumab promising for myasthenia gravis.

With that background in mind, let's dive into the MINT trial. It was a phase three, double-blind, randomized, placebo-controlled study conducted across 20 countries. A total of 238 adults with antibody-positive gMG—either acetylcholine receptor, also known as AChR, or muscle-specific kinase, also known as MuSK—were randomized 1:1 to receive either placebo or 300 milligrams of inebilizumab intravenously on days one and 15. AChR-positive patients also received inebilizumab on day 183. Patients gradually tapered glucocorticoids starting at week four to a target of five milligrams per day or less by week 24.

The primary endpoint was change in Myasthenia Gravis Activities of Daily Living, also called MG-ADL, score at 26 weeks, and a key secondary endpoint was the change in the Quantitative Myasthenia Gravis, or QMG, score at 26 weeks. For context, the MG-ADL is a patient-reported outcome measured on a zero to 24 scale, and the QMG is a physician-assessed muscle strength scale measured from zero to 39.

So, what did the study find? Well, firstly, patients receiving inebilizumab did show greater improvement than those on placebo at 26 weeks. On the MG-ADL scale, scores significantly decreased by 4.2 points with inebilizumab compared with 2.2 points on placebo. And patients receiving inebilizumab had a 4.8-point QMG reduction compared to 2.3 points with placebo.

Subgroup analyses echoed the same direction of effect. In AChR-positive patients, the MG-ADL improved by 4.2 points compared with 2.4 on placebo. MuSK-positive patients saw a 3.9-point improvement versus 1.7 on placebo. Interestingly, the QMG benefit in MuSK-positive patients did not reach statistical significance.

By week 52, AChR-positive participants on inebilizumab continued to widen the treatment gap, with differences growing to -2.8 on MG-ADL and -4.3 on QMG. That sustained efficacy beyond the steroid taper hints at durable disease control.

Now, looking at safety, adverse events occurred in about 81 percent of inebilizumab recipients versus 73 percent with placebo. Headache, nasopharyngitis, urinary tract infection, infusion reactions, and cough were most common. However, serious adverse events were actually numerically lower in the inebilizumab group—8.4 percent compared to 13.4 percent with placebo—with no clear signal of increased severe infections or hypersensitivity.

Notably, three deaths occurred during the trial—two in the placebo group and one in the inebilizumab arm. However, investigators judged these events as likely unrelated to the study drug.

Overall, uncertainty remains about the durability of these benefits, how the safety profile will appear in real-world practice, and how inebilizumab will ultimately be positioned alongside other newer options such as FcRn antagonists and complement inhibitors.

But the MINT trial adds persuasive evidence that targeting CD19-positive B cells with inebilizumab can meaningfully improve patient-reported daily function and clinician-assessed strength in gMG. The therapy's mechanism offers a broader sweep of B-cell depletion than CD20 therapies, positioning it as a unique immunologic strategy.

This has been an *AudioAbstract* for *Neurofrontiers*, and I'm Ryan Quigley. To access this and other episodes in our series, visit *AudioAbstracts* or *Neurofrontiers* on ReachMD.com, where you can Be Part of the Knowledge. Thanks for listening!

### Reference

Nowak RJ, Benatar M, Ciafaloni E, et al. A Phase 3 Trial of Inebilizumab in Generalized Myasthenia Gravis. *N Engl J Med.* 2025;392(23):2309-2320. doi:10.1056/NEJMoa2501561