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Intravenous Immunoglobulin Therapy in Patients With Painful Idiopathic Small Fiber Neuropathy

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Study Question

Is IV immunoglobulin (IVIg) treatment a safe and effective option for patients with idiopathic small fiber neuropathy (SFN)?

What Is Known and What This Paper Adds

Several open-label studies and a recent retrospective study found that IVIg may be an effective treatment for immune-mediated SFN. However, this trial's results show that IVIg treatment does not provide greater-than-placebo pain intensity reductions in patients with idiopathic SFN.

Methods

For this double-blind clinical trial, the investigators recruited 60 patients meeting international diagnostic criteria of idiopathic SFN through an academic medical center in Maastricht, the Netherlands. Trial procedures occurred between July 2016 and November 2018. The investigators used computerized randomization to assign equal numbers of participants to groups receiving either a 2-g/kg IVIg infusion or a placebo (saline) infusion. The participants also received 3 additional infusions of 1-g/kg IVIg or placebo at 3-week intervals. The primary outcomes were between-group comparisons of from-baseline changes in Pain Intensity Numerical Rating Scale (PI-NRS) scores at 12 weeks, with the investigators regarding 1-point decreases as evidence of pain alleviation. The investigators also conducted between-group comparisons of scores on measures of general wellbeing, autonomic symptoms, and overall functioning and disability.

Results and Study Limitations

In both treatment groups, 29 participants completed trial procedures. The percentage of participants of the IVIg and placebo groups were similar in mean from-baseline PI-NRS score decrease of at least 1 point (40% vs 30%; $p = 0.588$). The IVIg and placebo groups were also similar in terms of secondary outcomes. The 2 groups were similar in terms of adverse event risks. This study provides Class I evidence that for patients with painful idiopathic SFN, compared to placebo, IVIg did not significantly reduce pain. This trial's limitations include a small patient sample, the possible failure to exclude participants with fibromyalgia, and a lack of prior evaluation of psychiatric comorbidities.

Table Between-Group Outcomes Comparisons

PI-NRS outcome	Odds ratio (95% confidence interval) for outcome when comparing IVIg group with placebo group
≥1-Point score decrease	1.56 (0.54–4.63)
≥2-Point score decrease	1.52 (0.43–5.78)

Comparisons of the IVIg and placebo groups in terms of likelihoods of achieving given 12-week PI-NRS outcomes.

Registration, Study Funding, and Competing Interests

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A draft of the short-form article was written by M. Dalefield, a writer with Editage, a division of Cactus Communications. The corresponding author(s) of the full-length article and the journal editors edited and approved the final version.

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