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Randomised placebo-controlled trial of monthly intravenous immunoglobulin therapy in relapsing-remitting multiple sclerosis. Austrian Immunoglobulin in Multiple Sclerosis Study Group.

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BACKGROUND: Multiple sclerosis is an autoimmune disorder characterised by the repeated occurrence of demyelinating lesions within the central nervous system. Uncontrolled studies and experimental evidence suggest beneficial effects of repeated administration of intravenous immunoglobulin (IVIg) by immunomodulating mechanisms and induction or remyelination. We aimed to investigate the efficacy of IVIg in a randomised double-blind multicentre study. **METHODS:** Patients with relapsing-remitting multiple sclerosis were randomly assigned a monthly dose of IVIg (0.15-0.2 g/kg bodyweight) or placebo. Duration of treatment was 2 years. The primary outcome measures were the effect of treatment on clinical disability-measured by the absolute change in Kurtzke's expanded disability status scale (EDSS) score- and the proportion of patients with improved, stable, or worse clinical disability (> or = 1.0 grade on EDSS score). **FINDINGS:** Of the 243 patients screened, 150 met our eligibility criteria and were randomly assigned to IVIg or placebo. Before the start of treatment two patients in the placebo group dropped out, so there were 75 patients in the IVIg group and 73 in the placebo group. Intention-to-treat analysis showed that IVIg treatment had a beneficial effect on the course of clinical disability. The EDSS score decreased in the IVIg-treated patients and increased in the placebo group (-0.23 [95% CI -0.43 to -0.03] vs 0.12 [-0.13 to 0.37], $p = 0.008$). In the IVIg group, the numbers of patients with improved, stable, or worse clinical disability were 23 (31%), 40 (53%), and 12 (16%) compared with ten (14%), 46 (63%), and 17 (23%) in the placebo group. Side-effects were reported in three (4%) IVIg-treated patients and in four (5%) placebo-group patients, but were not directly linked to study medication. **INTERPRETATION:** Monthly IVIg is an effective and well-tolerated treatment for patients with relapsing-remitting multiple sclerosis.

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