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Treatment of chronic progressive multiple sclerosis with intravenous immunoglobulins--interim results on drug safety of an ongoing study. IVIG study group.

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In a blinded administrative look we analyzed the safety profile of intravenous immunoglobulin (IVIG) treatment in an ongoing randomized, placebo controlled double blind study on the treatment of multiple sclerosis (MS) patients with primary or secondary chronic progressive MS. Up to October 1999 131 patients were included in the study. Collectively, these patients received approximately 1,200 infusions either with IVIG (400 mg/kg bodyweight every 4 weeks) or with placebo; approximately 600 IVIG infusions were administered. All reported serious adverse events (SAE), including reports on adverse events submitted directly to the drug safety department of the sponsor, were closely analyzed. A total of 25 SAE's (in 25 patients) have been reported up until 15th October 1999, whereby the main criterion for 'serious' in all of these cases was hospitalization. None of these 25 SAE were regarded as drug related. No side effects relating to liver functions, kidney functions or rheological problems have been reported. Since the mean score on the EDSS-scale of the patients at the point of inclusion in the study was 5.6 (median EDSS: 6.0) we conclude that IVIG treatment, at a dose of 400 mg/kg bodyweight every 4 weeks, is a relatively safe therapy even for severely disabled multiple sclerosis patients.

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