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An 'n-of-1' placebo-controlled crossover trial of intravenous immunoglobulin as adjuvant therapy in refractory pemphigus vulgaris.

Arnold DF, Burton J, Shine B, Wojnarowska F, Misbah SA.

Department of Clinical Immunology, John Radcliffe Hospital, Headley Way, Oxford OX3 9DU, UK.

BACKGROUND: Pemphigus vulgaris (PV) is an organ-specific autoimmune blistering mucocutaneous disorder that is potentially fatal. High-dose intravenous immunoglobulin (IVIg) is increasingly used in the treatment of autoimmune diseases and it has been reported that it may also be effective in PV. **OBJECTIVES:** To evaluate prospectively the efficacy of IVIg for PV using an 'n-of-1' placebo-controlled trial. **METHODS:** A randomized, placebo-controlled, crossover trial of IVIg was conducted in a single patient with severe PV, comprising two phases of six consecutive months of either IVIg or placebo infusion. Before the commencement of the trial, the patient had received 18 months of IVIg but concerns about the continuing therapeutic efficacy of IVIg led to the double-blind placebo-controlled 'n-of-1' trial of IVIg. **RESULTS:** Pemphigus autoantibody titres were significantly higher when on placebo compared with IVIg treatment (median 1 : 80 vs. 1 : 20, $P = 0.007$), desmoglein 3 (126 vs. 79, $P = 0.004$) and desmoglein 1 antibody levels (126 vs. 94, $P = 0.004$). There was a significant improvement in subjective disease activity scores while on IVIg compared with placebo (mean overall score 11.6 vs. 20.6, $P < 0.0001$). **CONCLUSIONS:** The results of this study confirm a beneficial effect of IVIg in the management of refractory PV.

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