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Are needle-free injections a useful alternative for growth hormone therapy in children? Safety and pharmacokinetics of growth hormone delivered by a new needle-free injection device compared to a fine gauge needle.

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Abstract

The clinical safety, use and pharmacokinetics of a new needle-free device for delivery of growth hormone (GH) were compared with those of conventional needle injection devices. In an open-label, randomized, 4-period crossover study, 18 healthy adults received single subcutaneous injections of Genotropin administered by the Genotropin ZipTip needle-free device and by conventional injection. Bioequivalence was established between the devices. In a separate open-label, randomized, multicenter, 2-period crossover study, pediatric patients underwent 2-weeks Genotropin treatment administered by the Genotropin ZipTip and by a fine-gauge needle device (>95% used the Genotropin Pen). In total, 128/133 patients who were treated completed the study. Genotropin ZipTip was well tolerated and >50% of patients found no difference between the devices for all parameters assessed. After study completion, >20% patients preferred to continue using Genotropin ZipTip. Although statistical analyses demonstrated superiority of the Genotropin Pen versus Genotropin ZipTip for bleeding, pain, soreness, and bruising, Genotropin ZipTip was considered to provide a safe and bioequivalent alternative to needle injection.