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Pharmacokinetics of human growth hormone administered subcutaneously with two different injection systems.

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Abstract

The bioavailability of recombinant human growth hormone (somatropin, CAS 12629-01-5) was compared between a transcutaneous jet injection device and subcutaneous cannula injection. Thirteen healthy male subjects received 8.64 IU somatropin once with jet and once with cannula injection in a randomized cross-over study. Baseline-corrected somatropin serum concentrations were evaluated with non-compartmental and compartmental methods. The 90% confidence intervals with two one-sided t-tests around the ratios of injection devices were 91-120% for maximum concentration, 94-110% for area-under-curve until 14 h, and 92-103% for area-under-curve to infinity. Somatropin has a known metabolic half-life of ca. 20-30 min while the observed terminal half-lives were 2-4 h. Absorption and elimination rate constants were similar. Times of maximum concentrations, terminal half-lives and lag times to start of absorption appeared to be shorter and the absorption rate constant appeared to be larger for jet than for cannula injection. In conclusion, the kinetics of somatropin from subcutaneous tissue had a "flip-flop" characteristic. Bioavailability of somatropin after jet injection was equivalent to cannula injection.

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