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## Pharmacokinetics and pharmacodynamics of a new formulation of recombinant human growth hormone administered by ZomaJet 2 Vision, a new needle-free device, compared to subcutaneous administration using a conventional syringe.

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### Abstract

The objective of the present study was to investigate the applicability of a new human growth hormone (Zomacton) formulation, administered both by a conventional syringe and by a new needle-free device (ZomaJet 2 Vision). The study was performed according to a randomized, controlled, three-period crossover design. On 3 separate days, all subjects received in a random order a single subcutaneous injection of 1.67 mg hGH as follows: Zomacton 4 mg/ml conventional syringe administration (Treatment A), Zomacton 10 mg/ml conventional syringe administration (Treatment B), or Zomacton 10 mg/ml ZomaJet 2 Vision administration (Treatment C). The pharmacokinetic parameters were assessed for the individual subjects in each group by noncompartmental methods. Bioequivalence was assessed based on log-transformed AUC and C(max) values. To investigate the effectiveness of two formulations and the different administration methods, the pharmacodynamic parameters (insulin-like growth factor-1 [IGF-1] and free fatty acids [FFA]) were also evaluated. No subjects were withdrawn due to adverse events. The local tolerance assessment (assessed by inspection) revealed no differences between ZomaJet2 Vision application and conventional injections by syringe. Administration of the new hGH formulation by syringe was found to be bioequivalent with the reference treatment, both based on AUC and C(max) values; the new formulation administered by use of ZomaJet 2 Vision was found to be bioequivalent based on AUC values only. When using the ZomaJet 2 Vision, the absorption of hGH was faster, resulting in higher C(max) values. The maximum hGH serum concentration of around 20 ng/ml was observed 3.5 to 4 hours after drug administration. The terminal half-life was found to be around 2.5 hours. Comparison of the pharmacodynamic profiles (both IGF-1 and FFA) demonstrated bioequieffectiveness. These results support the use of jet injectors as a viable alternative to the traditional injection pens.

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