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Local tolerance, pharmacokinetics, and dynamics of ganirelix (Orgalutran) administration by Medi-Jector compared to conventional needle injections.

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Abstract

The feasibility of administering a relatively high dose of the gonadotrophin-releasing hormone (GnRH) antagonist ganirelix by means of a needle-free injection device, which could be useful in the long-term treatment of sex-steroid-dependent disorders, was evaluated in a randomized, crossover study in 16 healthy females. Local tolerance and pharmacokinetics of ganirelix administered by MediJector versus conventional needle injections were compared. Additionally, the pharmacodynamic effect was evaluated. Two milligrams of ganirelix was administered s.c. once daily for 7 days by Medi-Jector or conventional needle in a randomized sequence, without a washout period. No apparent differences in local tolerance were observed. Most injections (87.5%) gave either no or only a mild reaction. Of the moderate reactions, swelling and redness were reported most frequently (overall 4.9 and 8.5% per injection, respectively). Administration by Medi-Jector was bioequivalent to conventional needle injection with respect to the peak concentration and area under the curve. A profound suppression of luteinizing hormone and follicle stimulating hormone was observed. Serum oestradiol and progesterone concentrations were relatively low prior to treatment and remained low during the entire study period. In conclusion, administration of a relatively high dose of ganirelix by Medi-Jector might be useful for long-term treatment of sex-steroid dependent disorders.

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