growth hormone (GH) treatment on height have not been studied in short Japanese SGA children.

Aim: The aim of this study was to investigate the long-term efficacy and safety of two doses of GH in short Japanese children born SGA.

Methods: This was a multicenter, double-blind, randomized trial comparing two doses of GH for the treatment of short stature in prepubertal (Tanner Stage 1) Japanese children born SGA with no catch-up growth. Initial GH treatment was 0.033 mg/kg per day (n = 39), 0.067 mg/kg per day (n = 38), or no treatment (n = 21) for 52 weeks. During a 208-week extension period, patients in the treated groups continued treatment at the same dose, and those in the no treatment group were randomized to receive either 0.033 (n = 10) or 0.067 mg/kg per day (n = 10) GH. The primary end point was the change in height standard deviation score (HSDS) for chronological age (CA). Secondary end points included change from baseline in height velocity (HV) SDS, bone age (BA), ratio of BA/CA, and metabolic parameters.

Results: A dose-dependent increase in mean HSDS for CA was seen in the two treated groups. After 260 weeks (5 years) of treatment, the mean HSDS for CA increased from –3.00 to –1.78 in the 0.033 mg/kg per day group and from –2.83 to –0.82 in the 0.067 mg/kg per day group. The initial no-treatment group showed a similar dose-dependent increase in HSDS after 4 years of treatment in the extension period. Bone age increased during GH treatment with the mean (standard deviation) change in bone age after 260 weeks being 5.79 (1.05) and 7.15 (1.05) years in the low- and high-dose groups, respectively. Both doses of GH were well tolerated with few treatment-related adverse events.

Conclusions: Long-term treatment with GH improved HSDS in a dose-dependent manner in short, prepubertal Japanese children born SGA and was well tolerated in this patient population.

Clinical Implications: Long-term GH treatment improves the height outcome of SGA children and is well tolerated.

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Comparison of Device Preference and Use Errors for a New Growth Hormone Injection Device Versus Comparator Devices

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Background: Recombinant growth hormone (GH) is used to treat short stature in children with GH deficiency and other conditions. Treatment adherence, which may be poor because of the need for daily injections and treatment length, may be improved with easy-to-use injection devices.

Aim: The aim of this study was to compare patient preference and use errors of a new GH injection pen (Norditropin FlexPro; Novo Nordisk A/S, Denmark) relative to four other pens: easypod (Serono, Switzerland), Genotropin pen (Pfizer, USA), Nutropin AQ NuSpin pen (Genentech, USA), and Omnitrope pen (Sandoz, Germany).

Methods: In two noninterventional, randomized, crossover studies, children (10–17 years) treated with GH (≥6 months) were randomly assigned to intuitiveness (n = 30, n = 32) or instruction (n = 26, n = 32) groups. All subjects performed a usability test involving needle attachment, dose setting, and injection into an Eppendorf tube. Intuitiveness groups had brief verbal instructions on device use. Instructed groups were instructed in full according to the user guide. Patient preference for devices was assessed by a 13-item questionnaire. The number and type of use errors were recorded.

Results: FlexPro was rated as the most preferred device in the majority of items in intuitiveness (9/13, 11/13) and instructed groups (10/13, 11/13) and was the most preferred device in both groups (intuitiveness: 15/30, 19/32; instruction: 19/26, 23/32). FlexPro scored highest for ease of use, easypod for best delivery feedback, Genotropin and NuSpin pens for appearance and quality. Technical errors were less with FlexPro (1 to 2 errors) than with comparator devices (9 to 39 errors) in intuitiveness groups, and fewer errors were recorded in instruction groups (1 to 2 errors for each device).

Conclusions: Both instructed and uninstructed patients preferred Norditropin FlexPro to comparator devices. The numbers of errors in the intuitiveness group reflect the problems/errors patients or caregivers face when they have not received training or do not understand it. Overall, use of FlexPro was associated with fewer errors than the comparator devices.

Clinical Implications: An easy and less error-prone device may help improve treatment adherence. Training can reduce error rate.

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Treatment of Children With Central Precocious Puberty: 3 Years of Continuous Suppression With Histrelin Subdermal Implants

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Background: Central precocious puberty (CPP) is defined as the reactivation of the hypothalamic–pituitary–gonadal (HPG) axis before age 8 in girls and age 9 in boys. Gonadotropin-releasing hormone analog (GnRHa) therapy is the standard of care for patients with CPP. In a Phase 3 open-label study, a 12-month histrelin subcutaneous implant (Supprelin LA) suppressed peak luteinizing hormone (LH) and sex steroid levels for 1 year; a subsequent implant suppressed the HPG axis through a second year. Herein reports on Year 3 of histrelin therapy.

Aims: The aim of this study was to report on the prospective extended-access phase of the open-label study involving a third 12-month histrelin implant.

Methods: Patients who completed the initial extension (second implant) portion of the study and for whom the decision was made to continue GnRHa therapy were offered the option for a third implant.

Results: Thirteen children (12 females [8 treatment-naive, 4 with prior treatment] and 1 male with prior treatment; at baseline, mean age = 6.6 years [range = 4.5–9.1]) received a third implant. LH suppression, assessed by GnRHa stimulation, was maintained in all patients throughout the third year of therapy (M = 0.36 vs. 13.71 mIU/mL at baseline; p = .0132). Mean estradiol levels in the girls remained suppressed (<4.73 pg/mL). Mean bone age to chronological age ratio after 36 months of therapy was significantly lower compared with baseline (1.21 vs. 1.41; p < .002). Consequently, Bailey–Pinneau predicted that adult height (PAH) after 36 months of therapy was significantly higher compared with baseline (156.87 vs. 150.05 cm; p < .015). During 3 years, 9 (69%) patients experienced implant site reactions (mild pain, itch, and discomfort)