

# Randomized Controlled Trial to Investigate the Effects of Growth Hormone Treatment on Scoliosis in Children with Prader-Willi Syndrome

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**Context:** The prevalence of scoliosis in children with Prader-Willi syndrome (PWS) is 30–80%, depending on age. Although reports about effects of GH treatment on scoliosis in children with PWS are limited, scoliosis is generally considered a contraindication for GH treatment.

**Objective:** The aim was to study the effects of GH treatment on the onset of scoliosis and curve progression in children with PWS.

**Design:** We conducted a multicenter, randomized, controlled GH study in infants and prepubertal and pubertal children. Infants and prepubertal children were randomized into a GH-treated group (1.0 mg/m<sup>2</sup> · d) and a control group for 1 and 2 yr, respectively. Pubertal children were randomized to receive somatropin 1.0 or 1.5 mg/m<sup>2</sup> · d. Yearly, x-rays of the spine were taken, and height, weight, truncal lean body mass (with dual energy x-ray absorptiometry), and IGF-I were measured.

**Patients:** A total of 91 children with PWS (median age, 4.7 yr; interquartile range, 2.1–7.4) participated in the study.

**Main Outcome Measures:** We measured the onset of scoliosis (Cobb >10°) and scoliotic curve progression.

**Results:** GH-treated children had similar onset of scoliosis and curve progression as randomized controls ( $P = 0.27$ – $0.79$  and  $P = 0.18$ – $0.98$ , respectively). GH treatment, IGF-I SD score (SDS), and catch-up growth had no adverse effect on the onset of scoliosis or curve progression, even after adjustment for confounders. Height SDS, truncal lean body mass, and IGF-I SDS were significantly higher in GH-treated children than in randomized controls. At baseline, a higher IGF-I SDS was associated with a lower severity of scoliosis.

**Conclusions:** Scoliosis should no longer be considered a contraindication for GH treatment in children with PWS.