

Evaluation of Growth Hormone Deficient pre pubertal children treated with Omnitrope® using the AuxoLog computer program

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OBJECTIVES

Background

AuxoLog is a validated computer program that evaluates auxologic parameters comparing them with the Spanish growth charts. It also allocates subjects to the corresponding pubertal development group.

Objective

To assess the evolution of auxological parameters in Growth Hormone Deficient (GHD) pre pubertal children treated with Omnitrope® for a minimum of two years prior to puberty.

METHODS

Non-interventional, retrospective, longitudinal, multicentre study.

Patient data was collected from the medical records of patients and registered in the AuxoLog program.

Data analysis was conducted and compared, according to the corresponding pubertal mature group, with the Carrascosa et al. 2011 (N=194) and Carrascosa et al. 2013 (N=100) study results^{1,2}

RESULTS

16 patients were recruited, with a mean age of 13,2 years. 56,32% (9) were males.

The age at the beginning of treatment with Omnitrope® was $9,1 \pm 0,98$ years, with a length of treatment of $47,1 \pm 8,7$ months, keeping a dosage of 0,03mg/kg/day (+/- 0,01 mg).

The growth evolution in the first two years of treatment is depicted in the next table:

	Mean \pm SD (n=14)	Carrascosa et al. 2011 Mean \pm SD (n=194)	Carrascosa et al. 2013 Mean \pm SD (n=100)
Age at the beginning of treatment (years)	$9,1 \pm 0,98$	$6,9 \pm 2,1$	$7,4 \pm 1,6$
Height SDS at the beginning of treatment	$-2,87 \pm 0,4$	$-3,19 \pm 0,74$	$-3,3 \pm 0,6$
Height SDS at the end of the first year of treatment	$-2,08 \pm 0,44$	$-2,37 \pm 0,76$	$-2,45 \pm 0,5$
Increase in Height SDS in the first year of treatment	$0,79 \pm 0,4$	$0,82 \pm 0,3$	$0,85 \pm 0,3$
Height SDS at the end of the second year of treatment	$-1,76 \pm 0,47$	$-1,92 \pm 0,78$	$-1,95 \pm 0,6$
Increase in Height SDS in the second year of treatment	$0,32 \pm 0,4$	$0,45 \pm 0,4$	$0,5 \pm 0,4$
Increase in Height SDS in the first two years of treatment	$1,11 \pm 0,4$	$1,27 \pm 0,5$	$1,35 \pm 0,4$
Height SDS at the beginning of the pubertal growth spur	$-1,53 \pm 0,49$	-	$-1,65 \pm 0,55$
Increase in Height SDS from beginning of treatment to pubertal growth spur	$1,34 \pm 0,5$	-	$1,54 \pm 0,6$

Six patients reported a total of 11 Adverse Events. All were non-serious and classified as mild (63,6%) to moderate (36,4%); 2 possibly related to treatment (headache, lumbar pain).

CONCLUSIONS

Omnitrope® showed efficacy and safety in the treatment of pre pubertal children diagnosed with GHD.
The Auxolog program is a useful tool evaluating and following up patients with GHD treated with GH.

REFERENCES

1. Carrascosa A. et al (Catalan Group for Short Stature Study). 2011 Feb. Growth hormone secretory status evaluated by growth hormone peak after two pharmacological growth hormone release stimuli did not significantly influence the two-year catch-up growth induced by growth hormone therapy in 318 prepubertal short children with idiopathic growth retardation. *Horm Res Paediatr.*75(2):106-14.
 2. Carrascosa A. et al (Group for Short Stature Study). 2013. Height gain at adult-height age in 184 short patients treated with growth hormone from prepubertal age to near adult-height age is not related to GH secretory status at GH therapy onset. *Horm Res Paediatr.*79:145-56.
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