Switching from the original to the biosimilar recombinant human Growth Hormone - Omnitrope®: an experience of a single paediatric centre in Spain

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Introduction

- Recombinant human growth hormone (rhGH) has been used for several years in the treatment of growth disorders in children and adolescents with Growth Hormone Deficiency (GHD)[1].
- Omnitrope® is a rhGH approved by EMA (European Medicines Agency) in 2006. It was the first drug ever to be approved via the biosimilar regulatory pathway[3].
- In 2009/2010 Hospital Universitario Virgen del Rocío, Spain, changed the treatment of children with GHD from various original rhGHs to Omnitrope®.

Objectives

- To evaluate the consequences on growth parameters of switching treatment from original rhGHs to Omnitrope® in children with GHD, in a window period of 36 months (-18/+18 months).

Methods

- This study was a single centre, retrospective, observational study.
- It included children with GHD treated with an original rhGH at least 2 years before the switch to Omnitrope®.
- All treatment and follow-up was conducted according to routine clinical activity of the centre.
-Omnitrope® was administered in accordance with Summary of Product Characteristics of the drug and the guidelines of the centre.
- Height parameters were collected and calculated (Height: H, Height Standard Deviation Score: HSDS, Height Velocity: HV, Height Velocity Standard Deviation Score: HVSDS) from 18 months previous to switch to 18 months after the switch.
- Auxologic data were calculated from the measured height and using known data of the Spanish population (Spanish growth study 2010).
- Adverse events were also recorded.

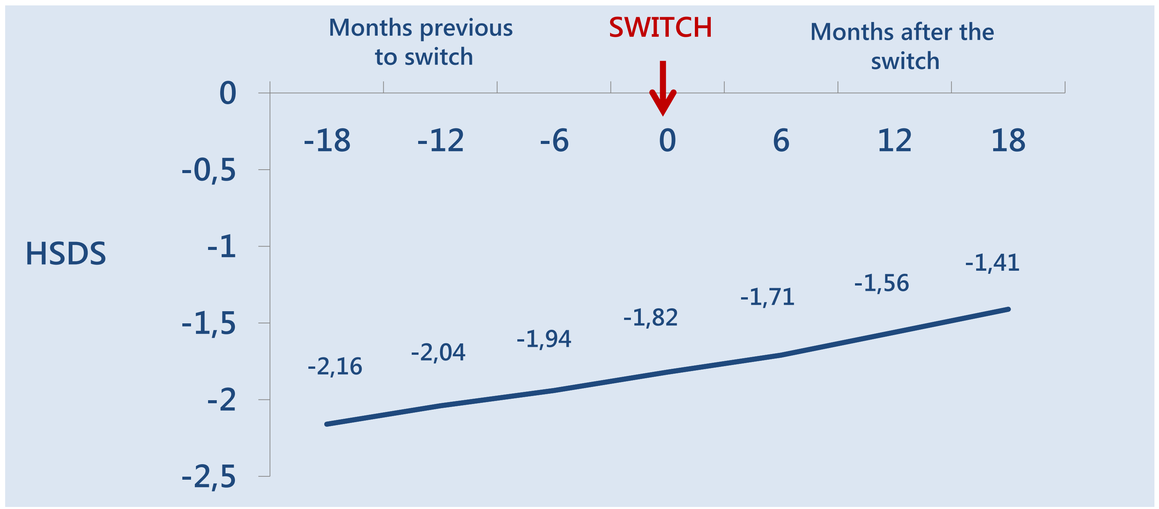
Results

- Data from 20 patients, 15 boys and 5 girls were gathered.
- The mean age of the patients was 14,5 years.
- 65% (13) had idiopathic GHD.
- The mean duration of treatment prior to switching was 38,3 months.

- Auxological data of patients on the 18 months before and after the switch to Omnitrope® are shown in the next table:

	Mean± s.d.			
Months	Height (cm)	HSDS	HV (cm/year)	HVSDS
- 18	118,5±10,9	-2,16±0,80	8,77±2,04	3,87±2,66
- 12	121,9±10,3	-2,04±0,78	7,10±1,26	1,98±1,58
- 6	122,4±30,6	-1,94±0,91	6,40±1,81	1,28±1,37
0	128,1±10,6	-1,82±0,88	6,20±1,39	1,03±1,80
+ 6	131,9±11,5	-1,71±0,89	7,68±6,33	1,05±1,86
+ 12	135,4±11,5	-1,56±0,88	6,82±1,72	0,95±1,32
+ 18	139,4±12,9	-1,41±0,91	7,01±2,17	0,94±1,60

- The HSDS evolution in the 36 month period evaluated is shown in the next figure:



Safety
- No adverse drug reactions were reported after the switch.
- 3 patients had transitory problems with the Omnitrope® device.

Conclusions

The switch of treatment from the originals to the biosimilar rhGH, Omnitrope®, had no negative impact on the growth or safety of children with GHD.

1. Bell J, Parker KL, Swinford RD, et al. Long-term safety of recombinant human growth hormone in children. *J Clin Endocrinol Metab* 2010; 95: 167–177.
2. European Medicines Agency 2008. Omnitrope® European Public Assessment Report 2008.

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