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).
- 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.
- 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:

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

- 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.


Study sponsored by Sandoz Farmacéutica SA