INTRODUCTION

• The ECOS observational study in Spain (NCT01376921) aims to evaluate adherence to recombinant human growth hormone (r-hGH) therapy prescribed via the easypod™ electromechanical auto-injector device.

• The easypod™ device administers pre-set doses of Saizen® r-hGH and stores accurate records of each dose and injection taken, which can then be shared with healthcare providers for the evaluation of adherence.1

• Although the easypod™ device makes the administration of r-hGH easier and more comforting for the patient, other factors can affect adherence leading to poor outcomes with respect to height velocity and final height. These factors include family socioeconomic status, education level and support, and treatment duration.1,4,5

OBJECTIVES

• To assess the use and acceptability of easypod™ and adherence to r-hGH therapy.

• To assess the overall socioeconomic background of caregivers responsible for administering injections.

• To highlight differences in individual patient’s dosing patterns.

METHODS

• Adherence was determined categorically and also as the percentage adherence over time, defined as the number of days with injections received divided by the number of days with injections planned.

• Accurate individual adherence data were transcribed directly from a patient’s easypod™, whereas socioeconomic, demographic, auxological and diagnostic data were obtained from medical records.

RESULTS

Patient Demographics

• The Spanish cohort consisted of 280 children, of whom 240 were included in the final analysis set (52% male) (Table 1).

• Despite high overall adherence (median 98.8%, mean 94.5% [95% confidence interval (CI) 92.9, 96.3]), growth responses varied and patterns of missed doses proved highly individual and, in some cases, fluctuated over time, possibly reflecting changes in caregiver or other life circumstances.

• Almost 80% of injection-giving caregivers were employed, while 31.0% had degree level education, 35.0% had only had school level education, 9.5% had ‘other’ education and for 22% this was not recorded.

• The main documented reason for the missed doses during years 2–5 was ‘Forgetting to take’ (111.6 [109.4, 113.9])

• The main documented reasons for the missed doses up to 4 years was ‘Forgetting to take’ (4 years 2 months) (Table 2). This patient developed puberty after the study period, and was taking gonadotropin-releasing hormone analogs as of November, 2015.

• The young patient’s height increased but did not rise above the 10th percentile for age during the study period (Figure 3).

• This patient had a moderate response to growth hormone treatment, with acceptable speed of growth in the first year, followed by a fall in the second year, and further increases.

• She presented with rapidly progressive pubertal development between 10.5 and 11.5 years of age.

• Her final height will most probably be close to the target height.

• The patient’s growth velocity before r-hGH therapy (cm/year) was 7.25 ± 2.24 (Table 2).

• Growth velocity before r-hGH treatment (cm/year) was 7.25 ± 2.24.

• Additional factors might have an influence on adherence,

• The majority of caregivers responsible for administering injections were married or cohabiting and were in employment, and similar proportions had either a primary or a university standard of education.

• Individual cases showed distinctive patterns of growth outcomes.

• Overall, the majority of children adhered extremely well to their treatment regimen using the easypod™ device.

• The majority of caregivers responsible for administering injections were married or cohabiting and were in employment, and similar proportions had either a primary or a university standard of education.

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CONCLUSIONS

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REFERENCES


2. Rodriguez-Amaro MD, et al. Poster presentation at the 98th meeting of the Endocrine Society, April 1–4, 2016, Boston, USA.


ACKNOWLEDGMENTS

The authors would like to thank the patients and their families for participating in the study. They would also like to thank the investigators and study teams at the participating centers, particularly Dr. José Luis Ruiz (Hospital Infanta Cristina, Madrid), Dr. Ignacio Diez López (Hospital Universitario Aranda, Araba/Azkoitia and Dr. Manual Carranza, Hospital Nuestra Señora de Meritxell, Andorra) for providing details of the case studies. The authors also thank Rosario Pérez Muñoz (TST Develop, Zaragoza, Spain) for medical writing support provided by Steven Goodrick of InScience Communications, London, UK, sponsored by Merck KGaA, Darmstadt, Germany.

DISCLOSURES

Merck KGaA, Darmstadt, Germany, Sanofi and Merrell Dow have received honoraria or research support from Merck KGaA, Madrid, Spain. VB and JAN are employees of Merck KGaA, Madrid, Spain. EB is an employee of Merck KGaA, Darmstadt, Germany.

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Table 1: Demographic Data Full Analysis Set (n=240)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Gender Male (%)</th>
<th>Ethnicity</th>
<th>Age (years)</th>
<th>Height before r-hGH treatment (cm)</th>
<th>Growth velocity before r-hGH treatment (cm/year)</th>
<th>Treatment only with Saizen easypod™</th>
<th>Parent marital status at baseline</th>
<th>Employment status at baseline – Father/legal guardian</th>
<th>Employment status at baseline – Mother</th>
<th>Educational status of person performing majority of injections</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>125 (52%)</td>
<td>Caucasian 225 (93.75%)</td>
<td>9.0 (8.6, 9.4)</td>
<td>111.6 (108.4, 113.0)</td>
<td>4.5 (4.2, 4.7)</td>
<td>Yes 234 (97.5%)</td>
<td>Married/cohabiting 191 (79.58%)</td>
<td>Employed 155 (70.02%)</td>
<td>Employed 151 (62.92%)</td>
<td>University degree T5 (31.25%)</td>
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<tr>
<td></td>
<td></td>
<td>African 1 (0.42%)</td>
<td></td>
<td></td>
<td></td>
<td>No 2 (0.83%)</td>
<td>Home maker 0 (0.00%)</td>
<td>Unemployed 17 (7.08%)</td>
<td>Home maker 30 (12.50%)</td>
<td>Primary education 94 (35.00%)</td>
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<tr>
<td></td>
<td></td>
<td>Asian 3 (1.25%)</td>
<td></td>
<td></td>
<td></td>
<td>Not known 31 (12.92%)</td>
<td>Unemployed 2 (0.83%)</td>
<td>Not known 39 (16.25%)</td>
<td>Unemployed 30 (12.50%)</td>
<td>Other 23 (9.98%)</td>
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<tr>
<td></td>
<td></td>
<td>Other 8 (3.35)</td>
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<td></td>
<td></td>
<td>Missing 7 (2.92%)</td>
<td>Missing 39 (16.25%)</td>
<td>Missing 3 (1.25%)</td>
<td>Missing 3 (1.25%)</td>
<td>Other 23 (9.98%)</td>
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<td>Missing 3 (1.25%)</td>
<td>Missing 3 (1.25%)</td>
<td>Missing 7 (2.92%)</td>
<td>Missing 4 (1.67%)</td>
<td>Missing 4 (1.67%)</td>
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</tbody>
</table>

Table 2: Demographic Data Full Analysis Set (n=240)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Males (%)</th>
<th>Duration of treatment: 4 years 11 months</th>
<th>Age at start of treatment: 4 years 6 months</th>
<th>The main documented reason for the missed doses during years 2–5 was ‘Forgetting to take’ (111.6 [109.4, 113.9])</th>
<th>The main documented reason for the missed doses up to 4 years was ‘Forgetting to take’ (4 years 2 months)</th>
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<td>125 (%)</td>
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CONCLUSIONS

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