

**INTRODUCTION**

- Easypod™ is the only electromechanical device for the delivery of recombinant human growth hormone (r-hGH). Saizen™ that tracks adherence.
- The easypod™ device was developed to improve patient convenience and comfort for long-term treatment with Saizen™.
- Ease and convenience of administering treatment can have a positive impact on the level of adherence, leading to more favorable growth outcomes.
- Easypod™ prospectively records the date, dose, and time of every Saizen™ administration to reliably monitor adherence to treatment.
- The Easypod™ Connect Observational Study (ECOS) is the first study to provide objective evidence of real-world adherence and effects on growth outcomes of the easypod™ device.
- This is the report of adherence outcomes in the cohort of ECOS patients in Slovakia.

**AIMS**

**Primary Outcome**
- To assess the level of adherence of participants receiving Saizen® via easypod™.

**Secondary Outcomes**
- To describe the correlation between adherence and 1-year growth outcomes (height standard deviation score (SDS) and height velocity (SV)).

**METHODS**

**Study Outline**
- ECOS was an observational, open-label, Phase IV study utilizing the easypod™ device to provide objective evidence of the levels of adherence to r-hGH therapy over 5 years.
- ECOS started in November 2010 and the last participant completed in February 2016.

- In the Slovak cohort, patients were 3–19 years old, with growth hormone deficiency, born small for gestational age (SGA) and girls with Turner syndrome (TS), received Saizen via the easypod™ electromechanical device. All patients were naïve when they started with the device.
- Patients attended one inclusion visit followed by between one and three follow-up visits per year, according to routine clinical practice.

**Data Collection**
- Data adherence were obtained prospectively via the easypod™ device to all subjects in the various data analysis sets (Figure 1).
- Demographic, auxological, and diagnostic data were obtained from the patients’ medical notes.

**Statistical Analyses**
- Baseline demographics and auxological information were measured in the complete analysis set (CAS), which comprised participants from the full analysis set (FAS) who met the following conditions.
- Easypod™ start date was available from the case report form.
- From the full analysis set (FAS) who met the following conditions.
- No gap in injection data of more than one week after the start of treatment.
- The height measurement closest to 1 year (±3 months) after treatment start date is not missing using a window of plus/minus 3 months (91 days).
- Median change in height SDS (Q1; Q3) was 0.49 (0.37;0.62) and change in median r-hGH SDS (Q1; Q3) was 2.54 (1.54;3.73).

**RESULTS**

**Participants**
- 2420 participants were enrolled in the ECOS globally. 80 participants aged 3–16 years were included in the FAS in the Slovak cohort.
- 53% of the Slovak cohort were included in the CAS – all subjects in the various data analysis sets (Figure 1).
- The median age of the Slovak cohort (n=80) was 9 years, which means that the majority of patients were of prepubertal age.
- 59% were female and 41% were male.
- The baseline demographics are shown in Table 1 and baseline auxological information is shown in Table 2.
- Indications: GHD (n=36), SGA (n=48), TS (n=8).

**Growth Outcomes**
- The 1-year median change in height SDS (Q1;Q3) was 0.49 (0.37;0.62) and the 1-year median change in height velocity SDS (Q1;Q3) was 2.54 (1.54;3.73).
- Analysis at 1 year in patients who had no missing data and no gaps in measurement -1 week CAS, N=52 produced similar results.
- Overall median adherence was 93% in SGA: 91% in TS.

**Conclusions**

- Overall median adherence was 93%.

- The Spearman product-moment correlation between adherence and change in height SDS was positive and significant (r=0.49; p<0.014).
- These findings are based on a small sample size but are consistent with findings in global data.

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**DISCLOSURES**

- U, IA, NC, AT, JK, SF, DP, and SR have no conflicts of interest to disclose. MB is an employee of Merck KgaA, Darmstadt, Germany.