Introduction and objectives

- **NutropinAq** (somatropin (rDNA origin) injection) is a human growth hormone (GH) indicated for the treatment of paediatric patients who have short stature or growth failure:
  - As a result of inadequate endogenous GH secretion
  - Associated with chronic renal insufficiency (CRI) up to the time of renal transplantation
- The **iNCGS** (International Cooperative Growth Study) is an international, multicentre, open-label, non-interventional post-marketing surveillance study (Fig. 1).
- The objective of the iNCGS is to collect long-term safety and effectiveness data on NutropinAq during treatment of paediatric growth disorders for which GH is indicated.
- The iNCGS registry started at the end of 2005. It currently includes seven European countries with a European Marketing Authorisation for NutropinAq: (Germany, Austria, France, Spain, Italy, Romania and the UK).
- Here we report patient baseline characteristics and exposure to NutropinAq® for each participating country.

Methods

- The iNCGS registry is ongoing but data were collected for the current analysis from 1st October 2005 to 31st December 2014.
- Boys and girls with paediatric growth disorders (and who fulfilled the inclusion/exclusion criteria of the iNCGS registry), for which GH therapy has been decided by the physician, and who were initiating or receiving NutropinAq® treatment were enrolled in the participating centres.
- This was a non-interventional study designed to document current clinical practice, thus:
  - The decision to prescribe NutropinAq® was taken before, and independently from, the decision to enrol the patient.
  - Prescribing of NutropinAq® was made in accordance with routine clinical practice.
  - The interventions were free to choose the treatment dose and duration, as well as the administration schedule, all of which were individualised for each patient.
- Follow-up examinations, patients were assessed for a number of safety and effectiveness variables, and treatment details were recorded. These variables were assessed at subsequent visits, the timing of which was determined by routine clinical practice.
- Treatment duration, and hence follow-up, was at the discretion of the treating physician, who could choose to discontinue treatment whenever deemed appropriate.
- Data were analysed descriptively:
  - For quantitative variables, the mean and standard deviation (SD), the two-sided 95% confidence interval (CI) of the mean, the median, quantiles Q1 and Q3, and the minimum and maximum were recorded.
  - For qualitative variables, the frequency, percentage of each modality, and the two-sided 95% CI were calculated.

Results

- As of 31st December 2014, 3250 patients were screened at 160 participating centres.
- 249 patients were excluded, leaving an enrolled population of 3001 patients from 153 centres in seven countries (Fig. 3).
- Patient characteristics at first dose of NutropinAq® are shown in Table 1.

Diagnosis and NutropinAq® treatment initiation

- Across all countries, the most frequent presentation was for idiopathic growth hormone deficiency (IGHD) (Fig. 2).

Height standard deviation score

- Comparing with the other countries in this study, in Germany and Romania there was a tendency for patients to have a lower height standard deviation score (SDS) (Table 3).
- Patients in France tended to have the greatest height SDS across most aetiologies.

NutropinAq® treatment

- In all countries, the mean treatment duration per patient tended to be between approximately 25 and 40 months (Table 2).
- Prescribed doses of NutropinAq® varied between highest in France, low in Austria and Italy, and a slightly higher dose in Germany. Across most aetiologies, doses at 2 years were more uniform across countries.

Conclusions

- The present study shows IGHD as the main aetiology for which NutropinAq® treatment is received among the European countries included in this analysis.
- The prescribed doses of NutropinAq tended to be highest in France and lowest in Germany across most aetiologies.
- There were no major differences in baseline characteristics between countries except patients appears to have more severe growth retardation in Germany (lowest height SDS).
- Although all patients were expected mean age at treatment initiation was different between the aetiologies, reflecting differences in the delay between diagnosis and treatment initiation.

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