Observational study on the prescription of the growth hormone Saizen® in adults in France

MEGHA Study

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Context

- Recombinant growth hormone (r-hGH) Saizen® has pediatric indications but also an indication for GH deficiency in adults.
- On HAS request, Merck Serono made an observatory study to describe prescription and monitoring conditions for patients treated by Saizen® in this indication.
- Included patients are followed-up for 5 years. These results describe final analysis.

Results

Included patients characteristics

- 90 GH deficient patients: 45 women; 49 childhood acquired deficiency (CO group), 41 adulthood acquired deficiency (AO group), mean age: 31.8±13 years old, mean BMI (body mass index): 26.4 kg/m² (±5.8). Patients were enrolled between December 2003 and October 2007 by 23 French hospitals.
- Patients were followed up 3.3 years (+1.9) on average to a maximum of 5.3 years (time between inclusion and last visit).
- IGF-1 was <2DS respectively for 62.5% and 41.7% of CO and AO patients.
- 95.6% of patients had at least one associated hypothalamic deficiency.
- 100% of AO group patients had at least one dynamic test and 98.8% of CO group patients (Fig.1).

Follow-up results

- IGF-1:
  One year after inclusion, IGF-1 levels remained <2DS for 48.1% of CO-group patients (4.5% in AO-group), showing that these patients had not received an adequate GH dose to treat their deficit (Fig.2).

- Imaging examination
  Depending on the follow-up year, 17 to 27% of patients had at least one imaging examination performed. The most common examination was an MRI. Analysis of tumor evolution in patients with acquired deficiency showed a stabilization for most of patients and no worsening.

- Treatment permanent discontinuation
  Treatment permanent discontinuation was observed for 45 patients (50% of patients), 24 in CO-group and 21 in AO-group. Patients had discontinued their treatment at a median of 13.0 months after inclusion (Q1=7.0, Q3=28.0) and discontinuation was asked by the patient in 71.1% of cases. The main reasons for discontinuation were an AE (9 patients, including 3 patients with a treatment-related AE), injection-related issues (6 patients), lack of efficacy (5 patients) and other non-specified reasons for 21 patients. Among these 45 patients, 26 discontinued treatment permanently, 13 took another GH after Saizen® discontinuation and no data were available for 6 patients.

- Quality of life (Fig.3)
  Overall, an improved quality of life (PGWB questionnaire) was observed for the first 6 months of treatment with a subsequent stabilization.

Fig.1: Distribution of number of GH stimulation tests per patient according to onset of GH deficiency

- Initial GH dose was between 0.15 to 0.3 mgid for 51.4% of patients, lower in 27.1% (median 0.24 mgid).

Fig.2: IGF-1 values in SDS (Ref. Brabant et al. Hormone Research 2003 80 53-60)

- BMI, waisthip ratio (WHR), blood pressure levels, lipid parameters, glycaemia were not significantly changed during follow-up period.

- ECGs: Depending on the follow-up year, 15 to 39% of patients had at least one ECG performed during the year. ECG result was normal for more than 85% of the examinations.

Conclusion

In the great majority of cases, prescription recommendations for Saizen® growth hormone in adults are observed. Experienced adverse events confirmed Saizen® safety as described in the Summary of Product Characteristics. However, obtaining earlier an effective dosage and closer monitoring are desirable.

Thanks

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Conflicts of interest

C. Cortet, M. Pugeat, J-L. Sadoul, J. Young, J.C. Souberbielle and P. Chanson were investigators of the MEGHA study.

L. Fresneau is employed at Merck Serono S.A.S. Lyon, France.