A pilot study for Comparing efficacy and safety of the CinnaTropin® to the reference recombinant human growth hormone in children with isolated growth hormone deficiency and multiple pituitary hormone deficiency

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Objectives: Comparing efficacy and safety of CinnaTropin® to Norditropin®

Study Design: Randomized, active-controlled, two-arm, open-label, and cross-over

Participants: A total of 30 participants (4-16 years) with IGHD & PHP

Intervention: Daily subcutaneous injections of either CinnaTropin® or Norditropin® (0.03mg/kg/day) 0.7IU/Kg/week, up to a maximum of 4 IU/day

Main outcome measures: Efficacy of each treatment was evaluated in terms of changes in height velocity, height and changes in serum levels of IGF-1 and IGFBP-3

Safety was assessed by the incidence of adverse events and laboratory parameters.

Inclusion criteria

- Pre-puberty or early-pubertal boys and girls between 4-16 years (Tanner stage 1 or 2)
- Height Standard Deviation Score (HSDS) ≤ -2 for chronological age at the time of diagnosis
- Ruling out other causes of short stature
- Approved GH Deficiency following Clandine stimulation test and low or low normal serum IGF-1 at the time of diagnosis
- Six months to one year follow up before treatment

Exclusion Criteria

- Any illness that prevent the proper conduct of the trial, such as seizure, acute or chronic infections, or in the case of AIDs, chronic liver disease, rheumatoid arthritis, or any systemic disease in any organ.
- Any active malignancy (such as leukemia, etc.)
- Contraindication of the administration of growth hormone (sleep apnea syndrome, etc.)
- Short stature due to chronic renal failure, other causes of GH deficiency such as chromosomal anomalies
- History of diabetes in patient or his/her first degree relatives
- Concomitant use of steroids other than replacement therapy in panhypopituitary patients

Baseline: Demographic information

- No significant difference was observed in demographic variables.

Results

- Height velocity comparison between treatment arms
- Height and growth velocity changes in treatment arms
- BMI Standard Deviation Score in treatment arms
- Evaluation of growth velocity between CinnaTropin® and Norditropin®

Conclusion

In our study safety and efficacy of CinnaTropin was similar to Norditropin (Novo Nordisk, Denmark)

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