

The Genetics and Neuroendocrinology of Short Stature International Study

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Synopsis:

The therapeutic approaches to growth enhancement in non-GH deficient patients are limited and mainly utilize the anabolic and growth promoting actions of GH. Although clinical trials in many different patient groups are currently being conducted, GH therapy has been approved by regulatory authorities for only a few indications: GH deficiency, Turner syndrome, chronic renal failure and achondroplasia.

The primary goal of this study is to evaluate the long-term safety and efficacy of Humatrope based on data collected in an observational setting.

Design of Study:

The GeNeSIS database will store clinical and biochemical data of diagnostic relevance that will be obtained during the routine management of children with short stature. In addition, specific data (see Section 8.5) will be collected for the development of accurate growth prediction models. Because GeNeSIS is a post-marketing research program, data will be collected as provided by the attending physician.

The following clinical data will be collected:

- historical data and etiology of the growth disorder, including congenital and acquired defects
- family and birth history
- the patient's medical history, including features that are not related to the growth disorder
- auxologic measurements
- clinical signs of sexual development
- bone age
- therapy regimen (hGH and other hormonal and non-hormonal medications)