A Study to Assess Growth in Children With Idiopathic Short Stature

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years to 16 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participants must be > 2 years old, and ≤ 14 years old (female) or ≤ 16 years old (males) at the time of signing the informed consent.
2. A height assessment corresponding to a height Z-score of ≤ -2.25 SDs in reference to the general population of the same age and sex, as calculated using the Centers for Disease Control and Prevention (CDC) growth chart (https://www.cdc.gov/growthcharts/zscore.htm).
3. Participants who have either never received hGH, or who are currently receiving hGH treatment.
4. Historic stimulation test result with serum or plasma GH level greater than 10 µg/L.
5. Parent(s) or guardian(s) are willing and able to provide written, signed informed consent.

Exclusion Criteria:

1. Diagnosis of systemic disease or condition that may cause short stature, eg renal, neoplastic, pulmonary, cardiac, gastrointestinal, immunologic and metabolic disease. Children with such diagnoses can be considered for inclusion if their condition is well controlled, at the discretion of the Medical Monitor.
2. Known presence of one or more pituitary hormone deficiencies
3. Bone age advanced over chronological age by more than 3 years.
4. For hGH naïve participants, historic stimulation test result with serum or plasma GH level greater than 10 µg/L or serum IGF-1 in the normal range for age (between -1.00 SDs and +2.00 SDs).
5. For participants currently on hGH treatment, historic results before GH treatment of stimulation test with serum or plasma GH level greater than 10 µg/L or serum IGF-1 test between -1.00 SDs and +2.00 SDs.
6. Have received an investigational product (IP) or investigational medical device for any purpose within 6 months before the Screening visit. .

Conditions & Interventions

Conditions:
Idiopathic Short Stature

More Information

Description:
Study 111-903 will generate baseline growth data in children with ISS by collecting growth measurements and other variables of interest.

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