

A Multicenter, Multinational, Observational Study to Characterize Growth in Children with Idiopathic Short Stature

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- participants must be at least 2 years old - no more than 14 years old if female, or less than 16 years old if male - height Z-score is at least -2.5 SDs compared to age and sex matched norms - able to walk ambulatory stand without assistance (not applicable for children who are less than 5 years of age and less than 104 cm i.e. 41 inches in length)

Exclusion Criteria:

- systemic disease or condition that may cause short stature, eg renal, neoplastic, pulmonary, cardiac, gastrointestinal, immunologic or metabolic disease - presence of one or more pituitary hormone deficiencies (ACTH [adrenocorticotropic hormone], ADH [antidiuretic hormone], FSH [follicle-stimulating hormone], GH [growth hormone], LH [luteinising hormone], TSH [thyroid-stimulating hormone]). - diagnosis of hypothyroidism, adrenal insufficiency or hypogonadism (treated or untreated). - Growth Hormone (GH) level below 10 ng/mL following a stimulation test. This does not apply to potential participants who are currently being treated with hGH for ISS - known chromosomal imbalance or genetic variant causing short stature syndrome, including but not limited to Laron syndrome, Prader-Willi syndrome, Russell-Silver syndrome, Turners syndrome, disproportionate skeletal dysplasias, abnormal short stature homeobox (SHOX) gene analysis, Rasopathy (including Noonan's Syndrome), or absence of GH receptors - bone age advanced over chronological age by more than 3 years - active cancer, chemotherapy or radiation therapy

Conditions & Interventions

Conditions:

Children's Health, Diabetes & Endocrine, Rare Diseases, Rare Diseases

Keywords:

Growth, Growth Hormone, Idiopathic Short Stature, ISS

More Information

Description: This research is being done to learn more about how children with idiopathic short stature grow. About 600 children with idiopathic short stature will be in this study across the world. The study will last a minimum of 6 months (i.e., three study visits). After a child has been in this study for at least 6 months, participants may be offered the option to exit this study and enroll in a different study with growth promoting agents.

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