

A Parallel-Arm, Phase 3, Open-Label, Active-controlled, Multicenter (Global), Randomized Clinical Trial to Investigate the Efficacy and Safety of Once-weekly Lonapegsomatropin Compared to Daily Somatropin in Prepubertal Participants with Growth Failure or Short Stature due to Growth Hormone Sufficient Causes- Turner Syndrome, SHOX Deficiency, Small for Gestational Age, and 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:

- 2 to 18 years of age - diagnosed with Turner syndrome, SHOX deficiency, born small for gestational age without catch-up growth, or idiopathic short stature - have not previously received growth hormone or growth hormone-promoting therapy - see link to ClinicalTrials.gov for complete inclusion criteria

Exclusion Criteria:

- receiving medications or have a medical condition that may affect growth - uncontrolled diabetes, thyroid disease, or other significant medical conditions - pregnant or breastfeeding - see link to ClinicalTrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:

Combination Product: Lonapegsomatropin [SKYTROFA®], Combination Product: Somatropin Pen Injector

Conditions:

Children's Health, Diabetes & Endocrine, Rare Diseases

Keywords:

Growth Hormone, SHOX deficiency, Turner syndrome

More Information

Description: This study is evaluating two growth hormone treatments in children with short stature due to Turner syndrome, SHOX deficiency, being born small for gestational age without catch-up growth, or idiopathic short stature. Researchers want to compare how well the two treatments support growth, monitor their safety, and better understand how they affect the body. Participation in the study will last approximately 52 weeks.

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Phase: PHASE3

IRB Number: STUDY00027579

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