An Open-Label Multiple-Dose, 52-Week Study to Evaluate the Safety, Pharmacokinetics, and Efficacy of XYOSTED® for Testosterone Replacement in Male Adolescents (ages: 12 to <18 years) with Conditions Associated with Deficiency or Absence of Endogenous Testosterone Due to Primary or Secondary Hypogonadism (Congenital or Acquired)

Status: Recruiting

Eligibility Criteria

Sex: Male
Age Group: Up to 18 years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

-12 to < 18 years of age - diagnosed with a deficiency or absence of testosterone due to hypogonadism - if receiving testosterone treatment, must be on a stable dose for at least 12 weeks before starting the study - body mass index (BMI)-for-age greater than the 5th percentile and weigh at least 40 kg (88 pounds) - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- suspected or known constitutional growth delay in growth and puberty (CDGP) - possible nutritional or gastrointestinal disorder that may impact growth - allergy to foods or products containing sesame seeds or sesame oil - history of suicidal behavior suicide attempts - have a history of drug or alcohol abuse - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:
Combination Product: Testosterone enanthate
Conditions:
Diabetes & Endocrine, Rare Diseases
Keywords:
hypogonadism, testosterone

More Information

Description: This is a study to see if a new drug, named XYOSTED Injection (study drug) will help in the treatment of male adolescents ages 12 to less than 18 years old who have low or no testosterone due to a medical condition called Hypogonadism. Male Hypogonadism is a condition in which the body doesn't produce enough of the hormone called testosterone that plays a key role in masculine growth and development during puberty. Participation in the study will last 52 weeks.
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