An Open-label, Single Arm, Multicenter, Phase III Study on the Efficacy, Safety,and Pharmacokinetics of FP-001 42 mg Controlled Release in Patients with Central (Gonadotropin-Dependent) Precocious Puberty

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- females aged 2 to 8 years or males aged 2 to 9 years old - diagnosis of Central Precocious Puberty (CPP) within 12 months - additional inclusion criteria (study staff will review)

Exclusion Criteria:

- major medical or psychiatric illness that could interfere with study visits - history of seizures, epilepsy, and/or central nervous system disorders that may be associated with seizures or convulsions - specific prior treatments (study staff will review)

Conditions & Interventions

Interventions:
Drug: Leuprolide Mesylate, Subcutaneous injection of 42 mg Leuprolide
Conditions:
Children's Health, Diabetes & Endocrine
Keywords:
Central Precocious Puberty, CPP, Early Puberty, Precocious Puberty, Puberty

More Information

Description: The study drug FP-001 (Leuprolide mesylate) is being developed for children that are suffering from central (gonadotropin-dependent) precocious puberty (CPP). Leuprolide has been approved in the United States (US) and the European Union (EU) as treatment for prostate cancer already, and other forms of Leuprolide from other companies have been approved for the treatment of CPP. In this clinical study, Leuprolide will be used in the form of a 6-month depot injection.
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