SPR001-205 A Phase 2 Study to Evaluate the Safety, Pharmacokinetics,;and Exploratory Pharmacodynamics of SPR001 (Tildacerfont) in Children: Aged 6 to 17 Years with Congenital Adrenal Hyperplasia

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- age 2 to 17 years - childhood diagnosis of classic congenital adrenal hyperplasia (CAH) a genetic mutation in CYP21A2 - currently taking steroids to treat CAH and on a stable dose for 1 month or more

Exclusion Criteria:

- clinically significant unstable medical or mental health condition (study staff will review) - females who are pregnant or nursing - unable to swallow medications

Conditions & Interventions

Interventions:
Drug: Tildacerfont
Conditions:
Rare Diseases, Children's Health
Keywords:
CAH, Congenital Adrenal Hyperplasia

More Information

Description: The goal of this study is to test the safety and effectiveness of tildacerfont in children with congenital adrenal hyperplasia (CAH). When a child is enrolled in the study, in addition to taking the study drug (tildacerfont), he or she will continue to take his or her standard glucocorticoid doses. A part of the study will be to test different doses of the study drug and to measure adrenal hormones at each visit. Children will be in the study for 18 weeks and will have to visit the study clinic 5 times.
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Phase: Phase II
IRB Number: SITE00001409

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