A Phase 2/3 Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of Atumelnant Treatment in Pediatric Participants with Congenital Adrenal Hyperplasia Including a Long-Term Extension

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- Male or female at birth, - less than 18 years old - diagnosis of classical congenital adrenal hyperplasia (CAH)

Exclusion Criteria:

- diagnosis of any other form of CAH

Conditions & Interventions

Interventions:
Drug: Atumelnant, Drug: Placebo
Conditions:
Children's Health, Diabetes & Endocrine, Rare Diseases, Rare Diseases
Keywords:
Classical CAH, classical congenital adrenal hyperplasia

More Information

Description: The purpose of this research is to evaluate the safety, efficacy, and pharmacokinetics of a new investigational drug called CRN04894, also called atumelnant for treating pediatric participants with Congenital Adrenal Hyperplasia (CAH). We want to see how safe atumelnant is at different doses and how well the body accepts (tolerates) it and how it moves through the body (how it gets in, spreads around, gets used, and then leaves), also known as pharmacokinetics (PK). We also want to see if if atumelnant produces the expected effect in the body, if it helps control the CAH, and if we can reduce the steroid (GC) dose.
Study Contact: CAH Research STUDY - cah-research@umn.edu
Principal Investigator: Kyriakie Sarafoglou
Phase: PHASE2
IRB Number: STUDY00026063