A Phase 3, Randomized, Double-blind, Placebo-controlled Study of ARD-101 for the Treatment of Hyperphagia in Patients with Prader-Willi Syndrome

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- at least 13 years of age - confirmed diagnosis of Prader-Willi Syndrome (PWS) - living in a stable care setting with the same caregiver(s) for at least 6 months and one designated caregiver is willing and able to adhere to study-related procedures and is willing to participate in all study visits and complete study-related questionnaires - females must not be pregnant when starting the study and willing to use effective birth control for 90 days after the last dose of study drug - males engaged in sexual relations with a female of childbearing potential must utilize a highly effective method of contraception until 90 days after the last dose of study drug - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- women who are pregnant or breastfeeding - difficulty swallowing or inability to swallow oral medication - significant medical or mental health diagnosis - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Conditions:
Children's Health, Diabetes & Endocrine, Rare Diseases, Rare Diseases
Keywords:
PWS, Prader-Willi Syndrome

More Information

Description: This study is for people who feel very hungry all the time, have trouble controlling eating (hyperphagia) and have Prader-Willi Syndrome (PWS). ARD-101 is being studied to see if it can help the body release certain gut hormones that may help reduce excessive hunger and food-seeking behaviors in people with PWS. The investigational treatment is a tablet taken by mouth and swallowed whole. The study will continue for up to 20 weeks (about 5 months).
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