A Trial of Setmelanotide in Patients With Congenital Hypothalamic Obesity (Sub-study of NCT05774756)

NCT06760546

Status	RECRUITING
Phase	Phase 3
Sponsor	Rhythm Pharmaceuticals, Inc.
Enrollment	39 participants

Key Eligibility Criteria

Inclusion (4)

- Diagnosis of multiple pituitary hormone deficiency (MPHD), or septo-optic dysplasia (SOD), or optic nerve hypoplasia (ONH), or Childhood-onset combined pituitary hormone deficiency (CPHD), or Pituitary Stalk Interruption Syndrome (PSIS) with at least one pituitary deficiency AND a body mass index (BMI) of e30 kg/m2 for patients e18 years of age, or BMI e95th percentile for age and sex for patients 4 to \<18 years
- Age 4 years and older
- Weight gain associated with the hypothalamic injury and a BMI of e30 kg/m2 for patients e18 years of age or BMI e95th percentile for age and sex for patients 4 to \<18 years of age
- Agree to use a highly effective form of contraception throughout the study and for 90 days after the study

Exclusion (12)

- Diagnosis of Prader-Willi syndrome (PWS) or Rapid-onset obesity with hypoventilation, hypothalamic, autonomic dysregulation, neuroendocrine tumor syndrome (ROHHADNET)
- Weight loss \>2% in the previous 3 months for patients aged e18 years or \>2% reduction in BMI for patients aged 4 to \<18 years
- Bariatric surgery or procedure within last 2 years
- Diagnosis of severe psychiatric disorders; any suicidal ideation, attempt or behavior
- Current, clinically significant pulmonary, cardiac, metabolic, or oncologic disease

... and 7 more (see full listing online)

Locations (11 total)

University of Alabama, Birmingham, Alabama, United States
Children's Hospital Colorado, Aurora, Colorado, United States
Lurie Children's Hospital, Chicago, Illinois, United States
... and 8 more locations