

Pharmacokinetics and Pharmacodynamics of Topiramate for Weight Loss in Youth: PHARMATOP

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- ages 12 to less than 18 years old - Body mass index (BMI) greater than or equal to 1.2 times the 95th percentile (age and sex-adjusted) and/or BMI greater than or equal to 35 kg/m² - deemed appropriate candidates to receive topiramate (without contraindications) for weight loss by an obesity medicine specialist at the University of Minnesota

Exclusion Criteria:

- history of metabolic/bariatric surgery - obesity associated with a diagnosed genetic disorder - clinically diagnosed hyperthyroidism or uncontrolled hypothyroidism - history of acute angle closure glaucoma - see link to clinicaltrials.gov for additional exclusion criteria

Conditions & Interventions

Interventions:

Drug: Topiramate Tablets

Conditions:

Diabetes & Endocrine, Children's Health

Keywords:

Weight management

More Information

Description: Topiramate is a commonly prescribed medication at weight management clinics. While doctors know that some people respond better to topiramate in terms of weight loss and changes in eating behaviors, the reasons WHY some respond better than others are not known. Knowing more about the relationships between topiramate doses, concentrations of topiramate in the blood stream, and an individual's response to this medicine will help doctors determine those who may be more likely to benefit. Doctors also want to know if someone's genes (their DNA) may help explain why some people respond better to topiramate than others. We expect that you will be in this research study for about 14 weeks (3.5 months).

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Phase: Early Phase 1

IRB

Number: STUDY00013488

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