Smart Use of Medication for the Treatment of Adolescent Severe Obesity

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 12 Years to 17 Years old
This study is NOT accepting healthy volunteers

Inclusion Criteria:

• Provision of signed and dated informed assent form;

• Provision of signed and dated informed parental consent form from at least 1 legal parent/guardian;

• Stated willingness to comply with all study procedures and availability for the duration of the study;

• BMI >/= 1.2 times the 95th percentile or BMI >/= 35 Kg/m2, whichever is lower;

• Tanner stage >/= 2;

• Male or female, aged 12-17 at time of consenting;

• For females of reproductive potential: when sexually active, agreement to use highly effective contraception (oral contraceptive pill, intra-uterine device (IUD), or implant) during study participation;

• For males of reproductive potential: use of condoms or other methods to ensure effective contraception with partner.

Exclusion Criteria:

• Contraindications to phentermine or topiramate use according to package inserts, including: history of glaucoma; current or recent (< 14 days) use of monoamine oxidase inhibitor; known hypersensitivity to sympathomimetic amines; current pregnancy, plans to become pregnant, or if sexually active refusal to use 2 forms of birth control; history of cardiac disease including coronary artery disease; clinically significant cardiac arrhythmias; heart failure or uncontrolled hypertension;

• Diabetes (type 1 or 2);

• Presence of cardiac pacemaker;

• Current or recent (<6 months prior to enrollment) use of weight loss medication(s);

• Current use of weight-altering medication(s) (e.g., atypical antipsychotic, metformin) unless dose has been stable for past 6 months;

• Current use of other sympathomimetic amine such as attention-deficit hyperactivity disorder (ADHD) stimulants;

• Seizure disorder (other than infantile febrile seizure);

• Previous bariatric surgery;

• Recent initiation of change in dose (< 3 months prior to enrollment) of anti-hypertensive or lipid medication(s);

• Tobacco use

• History of or current diagnosis of schizophrenia, psychosis, mania, chemical dependency;

• Unstable depression or anxiety that has required hospitalization in the past year;

• Any history of suicide attempt;

• Suicidal ideation or self-harm within 12 months prior to enrollment;

• Bicarbonate < 18 mmol/L;

• Creatinine > 1.2 mg/dL;

• History of cholelithiasis;

• History of nephrolithiasis;

• Untreated thyroid disorder;

• Hyperthyroidism;

• Breastfeeding

Conditions & Interventions

Interventions:
Behavioral: Lifestyle Modification Therapy (LSMT), Drug: Phentermine Pill, Drug: Topiramate Pill
Conditions:
Adolescent Obesity
Keywords:
Clinics and Surgery Center (CSC)

More Information

Description: This is a single site, 2-staged sequential multiple assignment randomized trial (SMART) that will systematically examine: 1) the optimal timing (12- versus 24 weeks) for identifying non-responders to lifestyle modification therapy (LSMT) before starting adjunct pharmacotherapy with phentermine and 2) for non-responders to LSMT+phentermine, the relative effect of adding topiramate to LMST+phentermine versus switching to LSMT+topiramate monotherapy. All participants will receive a total of 48 weeks of intervention.
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Phase: Phase 2
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