

## Role of Pharmacotherapy in Counteracting Weight Regain in Adolescents with Severe Obesity

**Status:** Recruiting

### Eligibility Criteria

**Age:** Up to 18 years old

This study is also accepting healthy

**Healthy Volunteers:** volunteers

#### Inclusion Criteria:

- severe obesity (BMI  $\geq$  120% of the 95th percentile or BMI  $\geq$  35 kg/m<sup>2</sup>) - 12 to less than 18 years of age at enrollment - female participants who are sexually active with males and who are able to get pregnant must agree to use two forms of contraception throughout the trial

#### Exclusion Criteria:

- diabetes (type 1 or 2) - current or recent (< six months prior to enrollment) use of anti-obesity medication(s) (use of naltrexone or bupropion alone is not an exclusion) - previous metabolic/bariatric surgery - current use of a stimulant medication - history of glaucoma - current or recent (<14 days) use of monoamine oxidase inhibitor - history of treatment with growth hormone - history of bulimia nervosa - major psychiatric disorder - any history of active suicide attempt - history of suicidal ideation or self-harm within the previous 30 days - current pregnancy or plans to become pregnant during study participation - current tobacco use - history of cardiac, endocrine, kidney disease (study staff will review)

### Conditions & Interventions

#### Conditions:

Children's Health, Diabetes & Endocrine

#### Keywords:

Clinics and Surgery Center (CSC), Obesity, overweight, weight loss

### More Information

**Description:** In this study we want to find out more about weight loss and how diet and medications can affect weight loss. This study will last for up to 58 weeks. There are two phases to the study: - A weight loss phase with prescribe meals that lasts 6 weeks. - A study medication/placebo phase that lasts up 52 weeks. You will not know if you are receiving the medication or the placebo.

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**Phase:** PHASE2

**IRB**

**Number:** STUDY00008743

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