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Treatment of Binge Eating Disorder in Obesity: Naltrexone/ Bupropion Combination Versus Placebo

This study is currently recruiting participants. (see Contacts and Locations)

Verified December 2014 by Yale University

Sponsor:
Yale University

Information provided by (Responsible Party):
Carlos Grilo, Yale University

ClinicalTrials.gov Identifier:
NCT02317744

First received: December 11, 2014
Last updated: NA
Last verified: December 2014
History: No changes posted

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Purpose

This study will test the effectiveness of the combination of Naltrexone and Bupropion relative to placebo for reducing binge eating in persons with obesity and binge eating disorder.

Condition	Intervention
Binge Eating Disorder	Drug: Naltrexone and bupropion combination Other: Pill Placebo

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: Treatment of Binge Eating Disorder in Obesity: Naltrexone/ Bupropion Combination Versus Placebo

Resource links provided by NLM:

MedlinePlus related topics: Eating Disorders

Drug Information available for: Naltrexone Naltrexone hydrochloride Bupropion hydrochloride Bupropion

U.S. FDA Resources

Further study details as provided by Yale University:

Primary Outcome Measures:

- Binge Eating Frequency (Categorical) [Time Frame: Post-treatment (at 3 months)] [Designated as safety issue: No]

  Binge eating will be assessed by interview and self-report and the primary outcome is frequency. Frequency is defined categorically (presence or absence of binge eating).

- Binge Eating Frequency (Categorical) [Time Frame: 6 month follow-up (an average of 6 months following treatment)] [Designated as safety issue: No]

  Binge eating will be assessed by interview and self-report and the primary outcome is frequency. Frequency is defined categorically (presence or absence of binge eating).

- Binge Eating Frequency (Continuous) [Time Frame: Post-treatment (at 3 months)] [Designated as safety issue: No]

  Binge eating will be assessed by interview and self-report and the primary outcome is frequency. Frequency also is defined continuously

(analyzed dimensionally).

- Binge Eating Frequency (Continuous) [Time Frame: 6 month follow-up (an average of 6 months following treatment)] [Designated as safety issue: No]

  Binge eating will be assessed by interview and self-report and the primary outcome is frequency. Frequency also is defined continuously (analyzed dimensionally).

Secondary Outcome Measures:

- Body Mass Index (BMI) [Time Frame: Post-treatment (at 3 months)] [Designated as safety issue: No]

  BMI is calculated using measured height and weight.

- Body Mass Index (BMI) [Time Frame: 6 month follow-up (an average of 6 months following treatment)] [Designated as safety issue: No]

  BMI is calculated using measured height and weight.

Estimated Enrollment: 50
Study Start Date: December 2014
Estimated Study Completion Date: April 2016
Estimated Primary Completion Date: April 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Naltrexone/ Bupropion combination 50 mg naltrexone and 300 mg bupropion per day for 3 months	Drug: Naltrexone and bupropion combination
Placebo Comparator: Pill placebo Daily placebo medication for 3 months	Other: Pill Placebo

Eligibility

Ages Eligible for Study: 21 Years to 65 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Binge eating disorder (full criteria as described in the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, 5th edition)
- BMI between 30 kg/m2 and 50 kg/m2
- Not taking anti-depressant medications
- Read English proficiently enough to read study assessments
- Available for duration of treatment plus follow-up period
- Able to travel to study location (New Haven, CT) for monthly visits
- Agree to study procedures

Exclusion Criteria:

- Medical status judged by study physician as contraindication
- History of seizures
- Past or current anorexia nervosa, bulimia nervosa
- Current medications that influence eating/weight
- Current substance use disorder or other severe psychiatric disturbance (e.g., suicidality) that requires immediate treatment
- Pregnant or breastfeeding

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a

study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02317744

Contacts

Contact: Janet A. Lydecker, Ph.D. 203-737-4299 janet.lydecker@yale.edu

Locations

United States, Connecticut

Yale School of Medicine **Recruiting**
New Haven, Connecticut, United States, 06520

Sponsors and Collaborators

Yale University

Investigators

Principal Investigator: Carlos M Grilo, Ph.D. Yale University

More Information

No publications provided

Responsible Party:	Carlos Grilo, Professor of Psychiatry and Psychology; Director of the Program for Obesity, Weight, and Eating Research, Yale University
ClinicalTrials.gov Identifier:	NCT02317744 History of Changes
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Additional relevant MeSH terms:

Binge-Eating Disorder
Bulimia
Eating Disorders
Hyperphagia
Mental Disorders
Signs and Symptoms
Signs and Symptoms, Digestive
Bupropion
Naltrexone
Antidepressive Agents
Antidepressive Agents, Second-Generation
Central Nervous System Agents
Dopamine Agents
Dopamine Uptake Inhibitors
Molecular Mechanisms of Pharmacological Action
Narcotic Antagonists
Neurotransmitter Agents
Neurotransmitter Uptake Inhibitors
Peripheral Nervous System Agents
Pharmacologic Actions
Physiological Effects of Drugs
Psychotropic Drugs
Sensory System Agents
Therapeutic Uses

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