

# A randomised, double-blind, placebo-controlled trial to evaluate the efficacy and tolerability of olanzapine as adjunctive treatment for anorexia nervosa in youth: a pilot study

<b>Submission date</b> 08/06/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/11/2005	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 11/09/2009	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

N/A

## Study information

## Scientific Title

### Study objectives

It is hypothesised that youth who present with a severe eating disorder and are treated with olanzapine will demonstrate reduced disordered eating attitudes and beliefs, and a higher rate of weekly weight gain, as compared to a control group treated with placebo. It is also hypothesised that those patients treated with olanzapine will demonstrate better short-term (14 weeks) and long-term (6 months) clinical outcome as compared to patients treated with placebo. It is also predicted that the physical side-effects of olanzapine will be minor given the relatively low dose (as compared to treatment for patients with schizophrenia), slow titration, and short-term use of olanzapine. Hospitalised patients on olanzapine may be discharged sooner than those on placebo.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Anorexia Nervosa

### Interventions

Olanzapine versus Placebo; Olanzapine will be started at a very low dose and gradually titrated up to a predetermined dose.

### Intervention Type

Drug

### Phase

Not Specified

### Drug/device/biological/vaccine name(s)

Olanzapine

### Primary outcome(s)

The change from baseline in the Eating Attitudes Test (EAT-26) score measured at week 12 and average weight gain over the first 12 weeks of treatment will be compared using Student's t-test (assuming a normal distribution of the measures; otherwise, Wilcoxon Mann Whitney test will be used). If necessary, a linear regression model will be fit to assess treatment effect adjusting for

variables thought to influence outcome that could result in imbalance between treatment groups at baseline. Treatment effect and its 95% confidence interval will be generated for each primary outcome.

### **Key secondary outcome(s)**

Although the study is not powered to detect differences in safety, we will nevertheless compare the frequency of adverse events between the two study groups using chi-square or Fishers exact test. Change from baseline in the EAT-26 score measured at week 15 and at the end of the maintenance period (week 40) as well as weight gain measured at the same time points will be analysed as for the primary outcomes. Change from baseline in the Computer Assisted Personal Interview (CAPI), Childrens Depression Inventory (CDI), Multidimensional Anxiety Scale for Children (MASC), the Eating Disorder Clinician-Parent Rating Sheet, and Child Behavior Checklist (CBCL) will be calculated for weeks 12 and 40. Assuming a normal distribution for each variable (except for the clinician/parent rating sheet), differences between study groups will be assessed using Students t-tests. Wilcoxon Mann-Whitney tests or log-transformation will be performed otherwise. The Eating Disorder Clinician/Parent Rating Sheet score will also be compared using a Wilcoxon Mann-Whitney test. A Poisson regression model will be used to compare the total number of hospital admissions between study groups. Rate of hospitalisation will be calculated for each patient as the total number of days in hospital divided by the total time in days spent in the study. Average rates and 95% confidence intervals will be generated for each study group. Rates will then be compared using a Poisson regression model. In order to avoid multiple testing issues, results will be compared with an alpha value adjusted for the number of tests performed using the Bonferonni criterion.

### **Completion date**

01/09/2007

## **Eligibility**

### **Key inclusion criteria**

1. Must give written informed consent or assent
2. Must be female
3. Must be between age 12 and 17 (younger than 18) at beginning of trial
4. Based on the Diagnostic and Statistical Manual of Mental Disorders (4th Edition Revised, American Psychiatric Association [APA], 2000) must have fulfilled the criteria for diagnosis of Anorexia Nervosa or Eating Disorder Not Otherwise Specified with a Body Mass Index  $\leq 17$

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

12 years

### **Upper age limit**

17 years

**Sex**

Female

**Key exclusion criteria**

1. Subject has known sensitivity to any of the products to be administered
2. Treatment with any other anti-psychotic medication, mood stabiliser, stimulant
3. Treatment with medication known to interact with olanzapine e.g. fluvoxamine, ciprofloxacin
4. Medical illness such as: diabetes, impaired glucose tolerance, hyperlipidemia, hepatic dysfunction, substance abuse, narrow angle glaucoma, paralytic ileus, or pancreatitis
5. Subjects inability to comply with trial requirements including lack of comprehension of English
6. Other unspecified reasons that, in the opinion of the Investigator, make subject unsuitable for enrollment
7. Subject is pregnant or is breast-feeding
8. Laboratory exclusion criteria:
  - a. Total white cell count <2.5
  - b. Neutrophil count <1.0
  - c. Liver function tests (aspartate transaminase (AST)/alanine transaminase (ALT) >2 X normal)
  - d. Positive pregnancy test
  - e. Electrocardiogram (EKG) QTc >440 msec or arrhythmia other than sinus bradycardia; conduction abnormalities prolonged QTc or other

**Date of first enrolment**

01/09/2005

**Date of final enrolment**

01/09/2007

**Locations**

**Countries of recruitment**

Canada

**Study participating centre**

**Psychiatric Director**

Ottawa

Canada

K1H 8L1

**Sponsor information**

**Organisation**

Children's Hospital of Eastern Ontario (Canada)

ROR

## Funder(s)

### Funder type

Charity

### Funder Name

W. Garfield Weston Foundation (Canada)

### Alternative Name(s)

The W. Garfield Weston Foundation, The Weston Family Foundation

### Funding Body Type

Private sector organisation

### Funding Body Subtype

Trusts, charities, foundations (both public and private)

### Location

Canada

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	31/01/2008		Yes	No