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

Submission date
08/06/2005

Registration date
04/11/2005

Last Edited
11/09/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 lose 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 Students 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 ≤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, narrrow 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 arrythmia 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
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K1H 8L1

Sponsor information

Organisation
Children's Hospital of Eastern Ontario (Canada)

ROR

https://ror.org/05nsbhw27

Funder(s)

Funder type
Charity

Funder Name
W. Garfield Weston Foundation (Canada)

Alternative Name(s)
The W. Garfield Weston 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?
Protocol article	protocol	31/01/2008		Yes	No