

# Atypical antipsychotics for continuation and maintenance treatment after an acute manic episode

<b>Submission date</b> 01/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/02/2009	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

Atypical antipsychotics for continuation and maintenance treatment after an acute manic episode: a randomised controlled trial

### Study objectives

We hypothesise that continuing risperidone or olanzapine for 6 or 12 months (along with a mood stabiliser) will lead to significantly lower rates of relapse or recurrence of mood episodes compared with mood stabiliser monotherapy for 12 months, in bipolar patients currently in remission but recently treated for an acute manic episode with a mood stabiliser and risperidone or olanzapine combination.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

University of Western Ontario, Office of Research Ethics gave approval on the 31st May 2005

### Study design

Randomised controlled trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Prevention

### Participant information sheet

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

Bipolar disorder

### Interventions

Patients will be randomised to one of three groups:

1. '0' week group: patients will receive lithium or valproate plus placebo for 52 weeks (risperidone or olanzapine tapering will begin on the day of randomisation with discontinuation of the drug within 2 weeks)
2. Continuation of the same atypical antipsychotic, risperidone or olanzapine, plus lithium or valproate for 24 weeks (tapering of the antipsychotic begins at the end of 24 weeks and completed within 2 weeks), followed by the same mood stabiliser plus placebo for another 28 weeks

3. Continuation of the atypical antipsychotic, risperidone or olanzapine, plus lithium or valproate for 52 weeks. The duration of the double-blind phase of the study will be 52 weeks and all patients will continue on the mood stabiliser, lithium or valproate, they had been on during the acute mania for the full duration of the study

### **Intervention Type**

Drug

### **Phase**

Not Applicable

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

Risperidone, olanzapine, lithium, valproate

### **Primary outcome measure**

Time to any mood episode.

### **Secondary outcome measures**

1. Time to premature discontinuation from the study for any clinical reason (dose change in medication, new intervention, side effects, etc.)
2. Time to manic episode
3. Time to depressive episode
4. Proportion of patients gaining more than 7% of body weight (this amount of weight gain is significant for cardiovascular morbidity)
5. Proportion of patients developing extrapyramidal symptoms, tardive dyskinesia, prolactin related side effects
6. Changes in YMRS, HAM-D 21, CGI-S, ESRS scores and weight during the study period

### **Overall study start date**

01/04/2002

### **Completion date**

30/03/2007

## **Eligibility**

### **Key inclusion criteria**

1. Patients who were recently (within the last 12 weeks) commenced on treatment for a Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) manic or mixed episode with a combination of lithium and risperidone, lithium and olanzapine, valproate and risperidone, or valproate and olanzapine
2. Patients who are in remission from mania for at least 2 weeks but no more than 6 weeks. Remission is defined as either:
  - 2.1. A Clinical Global Impression - Severity (CGI-S) scale score of 2 (borderline mentally ill) or less (normal, not ill) for 2 consecutive weeks
  - 2.2. A YMRS score of 8 or less (normal range) and a Hamilton Rating Scale for Depression (HAM-D) 21-item score of 8 or less (normal range) for 2 consecutive weeks
3. Must not be taking any other psychotropic medication with the exception of benzodiazepines (maximum of lorazepam 4 mg per day or its equivalent)
4. Patients aged 18 and above (efficacy of risperidone and olanzapine is not tested in those

below 18 years of age), either sex

5. Patients on 1 to 6 mg risperidone or 5 to 25 mg olanzapine (these are the dose ranges commonly used in clinical practice, and are shown to be effective doses in acute mania trials)

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

540

**Key exclusion criteria**

As we want the findings to be generalisable to clinically representative patients with bipolar disorder, we will not exclude any patients with a history of co-morbid substance abuse or medical illnesses. Any subjects who do not meet the above inclusion criteria will be excluded from the study.

**Date of first enrolment**

01/04/2002

**Date of final enrolment**

30/03/2007

**Locations****Countries of recruitment**

Canada

**Study participating centre****Mood Disorders Centre**

Vancouver, British Columbia

Canada

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**Sponsor information****Organisation**

University of British Columbia (Canada)

**Sponsor details**

2075 Wesbrook Mall  
Vancouver, British Columbia  
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**Sponsor type**

University/education

**Website**

<http://www.ubc.ca/>

**ROR**

<https://ror.org/03rmrcq20>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-53576)

**Funder Name**

Janssen-Ortho Canada, Inc. (Canada)

**Funder Name**

Eli Lilly Canada, Inc. (Canada)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

## **IPD sharing plan summary**

Not provided at time of registration