

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

Submission date 01/09/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/09/2005	Overall study status Completed	☐ Protocol
Last Edited 24/02/2009	Condition category Mental and Behavioural Disorders	☐ 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

Contact name

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Additional identifiers

Protocol serial number

MCT-53576

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Prevention

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(s)

Time to any mood episode.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

V6T 2A1

Sponsor information**Organisation**

University of British Columbia (Canada)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration