ISRCTN76555175 https://doi.org/10.1186/ISRCTN76555175

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

Submission date	Recruitment status	[ ] Prospectively registered
01/09/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
01/09/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/02/2009	Mental and Behavioural Disorders	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
V6T 2A1

Sponsor information

Organisation

University of British Columbia (Canada)

Sponsor details
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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