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OCTUMI-4: Evaluation of Mirtazapine and Folic Acid for Schizophrenia

Submission date 26/11/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 18/01/2010	**Overall study status** Completed	
Last Edited 04/10/2017	**Condition category** Mental and Behavioural Disorders	

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
RECOVERY [OCTUMI-4]

Study information

Scientific Title
OCTUMI-4: Evaluation of Mirtazapine and Folic Acid for Schizophrenia: A Large Simple 2x2 Factorial Trial

Acronym

OCTUMI-4

Study objectives
Primary hypothesis: Mirtazapine add-on therapy is superior to placebo in the treatment of symptoms in people with schizophrenia, measured by the Positive and Negative Syndrome Scale (PANSS).
Secondary hypotheses: Folic acid is superior to placebo as add-on therapy in the treatment of symptoms in patients with schizophrenia, measured by the PANSS.

Please note that as of 22/09/10 this record has been updated. Updates can be found in the relevant field with the above update date. Please also note that the trial will no longer be taking place in centres in China, as was intended at the time of registration.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Oxford Research Ethics Committee C, 26/07/2010, ref: 10/HO606/24

Primary study design
Interventional

Study design
Multicentre randomised double-blind placebo-controlled 2x2 factorial trial

Study type(s)
Treatment

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

Interventions
Participants are randomly allocated to mirtazapine or placebo and separately to folic acid or placebo
1. Mirtazapine or placebo
2. Folic acid or placebo
Both as add-on therapies to ongoing antipsychotic treatment

Both allocated medicines are taken orally for 12 weeks with a 2-week tapering period for mirtazapine on completion of the trial. The dose of mirtazapine is 30mg and of folic acid 400 - 500microg. (Participants for whom random allocation of folic acid/placebo is not appropriate can take part in the trial and be randomly allocated to lamotrigine or placebo only.)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mirtazapine, folic acid

Primary outcome(s)
Reduction of symptoms of schizophrenia assessed using the PANSS
Both primary and secondary outcomes will be measured at baseline and then at 4, 8 and 12 weeks

Key secondary outcome(s)
1. Reduction of negative symptoms of schizophrenia assessed using the PANSS
2. Change in depressive symptoms
3. Tolerability of trial treatment
4. Adverse effects including akathisia and extra pyramidal symptoms

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Diagnosis of DSM-IV schizophrenia
2. Active psychotic symptoms - i.e. hallucinations, delusions, thought disorder
3. Inpatient or outpatient
4. Aged 18 to 70 years.
5. Able and willing to consent to participate
6. Minimum score on PANSS 60
7. Drug treatment stable
8. Currently taking effective dose of antipsychotic
9. Adjunctive mirtazapine appears reasonable and both investigator and patient are uncertain whether it will offer any benefit
10. Clinically appropriate to change or augment treatment. Participants for whom random allocation of folic acid or placebo is not appropriate will be allocated mirtazapine or placebo only.

Ammended 22/09/10:
4. 16-70 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria

1. Not meeting criteria for current manic episode including schizoaffective disorder
2. No antidepressant treatment within last two weeks and not considering treatment for depression
3. Not taking clozapine
4. No contraindication to investigational medicinal products
5. Not pregnant, breast-feeding or planning a pregnancy

Date of first enrolment
01/04/2010

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
United Kingdom

England

Finland

Italy

Study participating centre
University of Oxford
Oxford
United Kingdom
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Sponsor information

Organisation
University of Oxford (UK)

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Research organisation

Funder Name
Stanley Medical Research Institute (USA)

Alternative Name(s)
The Stanley Medical Research Institute, SMRI

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration