

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

Submission date 26/11/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 18/01/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/10/2017	Condition category 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

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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

Study design

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

Primary study design

Interventional

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