

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

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|--|---|--|
| <b>Submission date</b><br>26/11/2009   | <b>Recruitment status</b><br>No longer recruiting             | <input checked="" type="checkbox"/> Prospectively registered |
|  |   | <input type="checkbox"/> Protocol                            |
| <b>Registration date</b><br>18/01/2010 | <b>Overall study status</b><br>Completed                      | <input type="checkbox"/> Statistical analysis plan           |
|  |   | <input type="checkbox"/> Results                             |
| <b>Last Edited</b><br>04/10/2017       | <b>Condition category</b><br>Mental and Behavioural Disorders | <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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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

**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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/04/2010

### **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

334

**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**

England

Finland

Italy

United Kingdom

**Study participating centre**

**University of Oxford**

Oxford

United Kingdom

OX3 7JX

# Sponsor information

## Organisation

University of Oxford (UK)

## Sponsor details

Clinical Trials and Research Governance

Manor House

John Radcliffe Hospital

Headington

Oxford

England

United Kingdom

OX3 9DU

## Sponsor type

University/education

## Website

<http://www.ox.ac.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

## 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