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

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

Contact name
Prof John Geddes

Contact details
University of Oxford
Department of Psychiatry
Warneford Hospital
Oxford
United Kingdom
OX3 7JX

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