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Mirtazapine augmentation enhances cognitive and negative symptoms in schizophrenic patients treated with risperidone: a randomised controlled trial

Submission date 27/05/2009	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 01/12/2009	**Overall study status** Completed	
Last Edited 01/12/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of mirtazapine augmentation of risperidone in the treatment of cognitive and negative symptoms of schizophrenia: a randomised controlled trial

Study objectives
Our hypothesis is that mirtazapine augmentation to the 'typical' atypical antipsychotics, risperidone that demonstrates potent inhibitors of of 5-hydroxytryptamine2 (5-HT2), alpha-2 adrenergic receptors can enhance cognitive function and reduce negative symptoms in patients with schizophrenia.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Bundang CHA Institutional Review Board (Ethics Committee) approved on the 22nd December 2008 (ref: 2008-15)

Study design
Double-blind randomised controlled 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
Mirtazapine was added to the on-going pharmacotherapy with risperidone in the mirtazapine group. The initial dosage was 15 mg/day at bedtime for the first two weeks. Thereafter, a daily dose of 30 mg/day was given at bedtime through the remainder of the study (six weeks). Doses of risperidone were fixed for the duration of the study.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Mirtazapine, risperidone

Primary outcome measure
1. Positive and Negative Syndrome Scale (PANSS), collected for each patient at week 0, week 2, week 4, and week 8
2. Scale for the Assessment of Negative Symptoms (SANS), collected for each patient at week 0, week 2, week 4, and week 8
3. Digit Span of K-WAIS (Korean-Wechsler Adult Intelligence Scale), collected at weeks 0 and 8
4. Controlled Oral Word Association Test (COWAT), collected at weeks 0 and 8
5. Korean-Complex Figure Test (K-CFT), collected at weeks 0 and 8
6. Korean-Auditory Verbal Learning Test (K-AVLT), collected at weeks 0 and 8
7. Estimated intelligence quotient (IQ) by the sum of Vocabulary scores and Block Design scores on the K-WAIS, collected at weeks 0 and 8
8. Timed Coding Test, collected at weeks 0 and 8

Secondary outcome measures
1. Barnes Akathisia Rating Scale, collected at weeks 0 and 8
2. Simpson-Angus Scale for Expyramidal Side-effects, collected at weeks 0 and 8
3. Clinical Global Impression (CGI), collected at weeks 0 and 8
4. Hamilton Rating Scale for Depression (HAMD), collected at weeks 0 and 8
5. Body weight, collected at weeks 0 and 8
6. Abdominal circumference, collected at weeks 0 and 8

Overall study start date
01/10/2008

Completion date
31/03/2009

Eligibility

Key inclusion criteria
1. Aged between 21 and 70 years, either sex
2. Diagnosed with schizophrenia based on the Structured Clinical Interview for Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) (SCID)
3. Receiving treatment of oral risperidone (Risperdal Quicklet®) or RLAI (risperidone long acting-injection) as outpatients. In addition, the subjects had to have been stable for at least eight weeks in an outpatient setting immediately prior to initiation of this study.
4. Presence of positive or negative symptoms or both, resulting in the illness of at least moderate severity (greater than or equal to 4 on the Clinical Global Impression [CGI] Severity Scale)

Participant type(s)

Patient

Age group
Adult

Sex
Both

Target number of participants
25

Key exclusion criteria
1. Evidence of organic mental disorder or mental retardation
2. Severe drug or alcohol dependence that required inpatient treatment and/or detoxification
3. Presence of a depressive episode. To exclude subjects with depressive episodes, the Hamilton Rating Scale for Depression (HAMD) was used (patients who scored more than 17 on HAMD were excluded).
4. Other conditions, such as a serious medical condition, a history of bipolar or schizoaffective disorder, substance misuse, suicidality, possibility of pregnancy, lactation, or inability /unwillingness to use contraception

Date of first enrolment
01/10/2008

Date of final enrolment
31/03/2009

Locations

Countries of recruitment
Korea, South

Study participating centre
Department of Psychiatry
Seongnam-Si
Korea, South
463-712

Sponsor information

Organisation
Bundang CHA Hospital (South Korea)

Sponsor details

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04yka3j04

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bundang CHA Hospital (South Korea)

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