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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

Registration date
01/12/2009

Overall study status
Completed

Last Edited
01/12/2009

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

ROR
https://ror.org/04yka3j04

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bundang CHA Hospital (South Korea)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration