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Quetiapine augmentation to serotonin reuptake inhibitors for patients with obsessive compulsive disorder: a double-blind, placebo-controlled study

Submission date
23/02/2007

Recruitment status
No longer recruiting

Registration date
23/02/2007

Overall study status
Completed

Last Edited
15/07/2021

Condition category
Mental and Behavioural Disorders

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

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
Quetiapine augmentation to serotonin reuptake inhibitors for patients with obsessive compulsive disorder: a double-blind, placebo-controlled study

Study objectives
Although Serotonin Reuptake Inhibitors (SRIs) are the most effective pharmacologic treatment currently available for patients with Obsessive-Compulsive Disorder (OCD), 40% to 60% of patients do not respond to this treatment.

This study was conducted to evaluate the efficacy and tolerability of quetiapine in addition to an SRI for medication-naive or free patients with OCD.

Hypotheses:
To determine the efficacy of quetiapine as an adjunct to patients with OCD, without comorbitity, who are newly diagnosed, medication-naive or free. The following hypotheses will be tested:
1. Addition of quetiapine to a SRI increases the number of responders to treatment
2. Addition of quetiapine to a SRI decreases the time to response
3. Addition of quetiapine to a SRI increases the effect size as measured with the Yale-Brown Obsessive Compulsive Scale (Y-BOCS)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised, placebo controlled, parallel group, double blinded trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive-Compulsive Disorder (OCD)

Interventions
The trial will be a randomised, double-blind, placebo-controlled, fixed dose study with quetiapine as adjunct to a SRI administered at the maximum tolerable dosage. Fluoxetine and venlafaxine will be excluded.

Ninety patients with OCD will be recruited and randomly allocated to receive either an SRI with placebo or an SRI with quetiapine for 10 weeks.

Both patient and investigator will be blind to the drug assignment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Quetiapine

Primary outcome(s)
The change in Y-BOCS from baseline to week 10 and the number of responders are the primary efficacy parameters. Criteria for response will be a 25% or greater change from baseline on the Y-BOCS and a final Clinical Global Impression (CGI) rating of much improved or very much improved.

Key secondary outcome(s))
1. The onset of response to treatment, using the time to a sustained response as criterion
2. Side effect profiles
3. Quality of life
4. Cognitive functioning

Completion date
31/12/2005

Eligibility

Key inclusion criteria
1. All patients meet the Diagnostic and Statistical Manual of mental disorders fourth edition (DSM IV) criteria for obsessive-compulsive disorder
2. Y-BOCS score more than 16 if obsessions and compulsions
3. Y-BOCS score more than 10 if only obsessions
4. Y-BOCS score more than 10 if only compulsions
5. Male and female, aged between 18 and 70 years
6. Female patients of childbearing potential must have a negative pregnancy test and use a reliable method of contraception
7. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment

Key exclusion criteria
1. Presence of any of the following DSM IV conditions:
1.1. Major depression (with a Hamilton Depression Rating Scale [HDRS] more than 17 [17 item])
1.2. Bipolar disorder
1.3. Schizophrenia or any other psychotic condition
1.4. Tic disorder, substance related disorder during the past six months
1.5. Epilepsy, or any structural Central Nervous System (CNS) disorder or stroke within the last year
2. Evidence of clinically significant and unstable cardiovascular, gastro-intestinal, pulmonary, renal, hepatic, endocrine or haematological disorders
3. Glaucome, myocardial infarction within the past year, or micturition abnormalities
4. Patients at risk for suicide
5. Multiple serious drug allergies or known allergy for the trial compounds
6. Use of antipsychotics during six months before the screening visit
7. Cognitive and behavioural treatment three months prior to the screening visit
8. Any known contra-indication against citalopram or quetiapine

Date of first enrolment
18/11/2003

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Netherlands

Study participating centre
University Medical Centre Utrecht (UMCU)
Utrecht
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Sponsor information

Organisation
University Medical Centre Utrecht (UMCU) (The Netherlands)

ROR
https://ror.org/04pp8hn57

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca R&D Mölndal (Sweden)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/07/2009	15/07/2021	Yes	No