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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

**Contact name**
Ms Nienke C C Vulink

**Contact details**
University Medical Centre Utrecht (UMCU)
Department of Psychiatry
Heidelberglaan 100
Utrecht
Netherlands
3584 CX
+31 (0)30 250 6370
n.c.c.vulink@azu.nl

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Other

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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.

### Secondary outcome measures
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

### Overall study start date
18/11/2003

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
90

### Total final enrolment
76

### 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

Netherlands
3584 CX

# Sponsor information

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

**Sponsor details**
Department of Psychiatry
Heidelberglaan 100
Utrecht
Netherlands
3584 CX
+31 (0)30 250 9019
h.g.m.westenberg@azu.nl

**Sponsor type**
Hospital/treatment centre

**Website**
http://www.umcutrecht.nl/zorg/

**ROR**
https://ror.org/04pp8hn57

# Funder(s)

**Funder type**
Industry

**Funder Name**
AstraZeneca R&D Mölndal (Sweden)

# 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

## Study outputs

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