

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

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Registration date 23/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/07/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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-naïve or free patients with OCD.

Hypotheses:

To determine the efficacy of quetiapine as an adjunct to patients with OCD, without comorbidity, who are newly diagnosed, medication-naïve 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. Glaucoma, 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

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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