Quetiapine augmentation to SRIs for patients with obsessive compulsive disorder: a double-blind, placebo-controlled study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28722

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Obsessive-Compulsive Disorder.

Sponsors and support

Primary sponsor: Prof. dr. H.G.M. Westenberg
Department of Psychiatry
UMC Utrecht
Heidelberglaan 100
3584 CX Utrecht
The Netherlands
Phone: +31 30 2509019
E-mail: h.g.m.westenberg@azu.nl
Source(s) of monetary or material Support: AstraZeneca

Intervention

Outcome measures

Primary outcome

The change in Yale Brown obsessive compulsive scale (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 CGI rating of much improved or very much improved.

Secondary outcome

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.

Study description

Background summary

Background:

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.

Methods:

Ninety patients with primary OCD according to DSM-IV criteria will be recruited between November 2003 and December 2005 and randomly assigned in a 10-week, double-blind, placebo-controlled trial to receive dosages titrated upward to 450 mg/day of quetiapine (N =

45) or placebo (N = 45) in addition to their SRI treatment.
During the study, primary efficacy will be assessed according to change from baseline on the Yale-Brown Obsessive Compulsive Scale (Y-BOCS). A responder is defined as having a final Clinical Global Impressions-Improvement scale rating of "very much improved" or "much improved" and a decrease of > or = 25% in Y-BOCS score.

Study objective

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 YBOCS.

Study design

N/A

Intervention

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.

Contacts

Public
University Medical Center Utrecht (UMCU), Department of Psychiatry,
Heidelberglaan 100
Nienke C.C. Vulink
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31 (0)30 2506370
Scientific

University Medical Center Utrecht (UMCU), Department of Psychiatry,
Heidelberglaan 100
Nienke C.C. Vulink
Heidelberglaan 100

Utrecht 3584 CX
The Netherlands
+31 (0)30 2506370

Eligibility criteria

Inclusion criteria

1. All patients meet the DSM IV criteria for obsessive-compulsive disorder;

2. Y-BOCS score > 16 if obsessions and compulsions;

3. Y-BOCS score > 10 if only obsessions;

4. Y-BOCS score > 10 if only compulsions;

5. Male and female, aged between 18-70 years;

6. Female patients of childbearing potential must have a negative pregnancy test and use a reliable method of contraception;

7. Written informed consent.

Exclusion criteria

1. Presence of any of the following DSM IV conditions:

a. Major depression (with a HDRS>17, [17 item]);

b. Bipolar disorder;

c. Schizophrenia or any other psychotic condition;

d. Tic disorder, substance related disorder during the past 6 months;

e. Epilepsy, or any structural 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 6 months before the screening visit;

7. Cognitive and behavioural treatment 3 months prior to the screening visit;

8. Any known contra-indication against citalopram or quetiapine.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-11-2003
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	10-08-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL85
NTR-old	NTR116
Other	: N/A
ISRCTN	ISRCTN40781401

Study results

Summary results
N/A