

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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28722

Bron

NTR

Verkorte titel

N/A

Aandoening

Obsessive-Compulsive Disorder.

Ondersteuning

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Overige ondersteuning: AstraZeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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-naïve 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 $\geq$ 25% in Y-BOCS score.

Doel van het onderzoek

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 YBOCS.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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. 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 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	18-11-2003
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	10-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A