A double blind, placebo controlled study of memantine in patients with obsessive-compulsive disorder.

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To determine the efficacy and safety of memantine for patients with OCD.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Anxiety disorders and symptoms
Study type	Interventional

Summary

ID

NL-OMON32677

Source
ToetsingOnline

Brief title
Memantine monotherapy in OCD

Condition

- Anxiety disorders and symptoms

Synonym
Obsessive-compulsive disorder, OCD

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: memantine, obsessive-compulsive disorder, OCD

Outcome measures

Primary outcome

The change in Yale Brown obsessive-compulsive scale (Y-BOCS) from baseline to week 12 and the number of responders are the primary efficacy parameters. Criteria for response will be a 35% or greater change from baseline on the Y-BOCS and a final CGI rating of *much improved or *very much improved*.

Secondary outcome

The onset of response to treatment, using the time to a sustained response as criterion, side effect profiles, Quality of life as measured with the Sheehan disability scale.

Study description

Background summary

Obsessive-compulsive disorder (OCD) is a chronic and disabling disease that puts a high economic burden on the patient and on society. Recent epidemiological studies have put the lifetime prevalence of OCD at 3%. Despite, the availability of antidepressants, a substantial proportion of patients with OCD do not respond to, or are intolerant of, standard treatments. Additional treatment strategies are therefore necessary.

Recent data (at genetic level, as well as using neuroimaging) shows that excessive action of the excitatory neurotransmitter glutamate may play a role in the pathophysiology of OCD. Memantine blocks the excitatory action of glutamate at the N-methyl- D-aspartate (NMDA) receptor under pathological conditions. Small case studies in OCD patients suggest that memantine may have efficacy in the treatment of OCD. These preliminary findings warrant larger, placebo-controlled studies in OCD.

Study objective

To determine the efficacy and safety of memantine for patients with OCD.

Study design

The trial will be a randomised, double blind, placebo-controlled, flexible dose study with memantine administered at 10 to 20 mg daily.

Intervention

Either memantine administered at 10 to 20 mg daily or identical placebo.

Study burden and risks

Using a very basic study design, harm will be limited. Blood will be drawn three times to asses adherence. The investigational product has a relatively mild side-effect profile, consisting of mainly dizziness, headaches, constipation, drowsiness and hypertension which are reported slightly more often than in placebo conditions.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

-patients meet the DSM IV criteria for obsessive-compulsive disorder with Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score > 16 if obsessions and compulsions and Y-BOCS score > 10 if only obsessions OR compulsions
- Male and female, aged between 18-70 years
- Female patients of childbearing potential must have a negative pregnancy test and use a reliable method of contraception.
- Written informed consent and proficient in Dutch

Exclusion criteria

- Y-BOCS > 30 or CGI-S (severity of psychopathology) of 6 (severely ill) of 7 (among the most extremely ill patients)
- Presence of any of the following DSM IV conditions; major depression (with a HDRS>15, [17 item]), bipolar disorder, schizophrenia or any other psychotic condition, tic disorder, substance related disorder during the past 6 months, epilepsy, or any structural CNS disorder or stroke within the last year.
- Evidence of clinically significant and unstable cardiovascular, gastro-intestinal, pulmonary, renal, hepatic, endocrine or haematological disorders, glaucoma, myocardial infarction within the past year, or micturition abnormalities
- Patients at risk for suicide
- Cognitive and behavioural treatment 3 months prior to the screening visit
- Use of antipsychotics during 6 months before the screening visit
- Use of any other psychotropic drug during 3 months before the screening visit
- Multiple serious drug allergies or known allergy for the trial compound
- Any known contra-indication against memantine

Study design

Design

Study phase:	3
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Namenda
Generic name:	memantine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	01-04-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2009-016751-22-NL
CCMO	NL30312.018.09