

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

Published: 02-03-2010

Last updated: 04-05-2024

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Anxiety disorders and symptoms
<b>Study type</b>	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

2 - A double blind, placebo controlled study of memantine in patients with obsessive ... 29-06-2025

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 assess 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**

### **Public**

Academisch Medisch Centrum

Meibergdreef 5  
1105 AZ  
NL

### **Scientific**

Academisch Medisch Centrum

Meibergdreef 5  
1105 AZ  
NL

## **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) or 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