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PRAZosin for patients with Obsessive Compulsive disorder

Submission date	Recruitment status	[ ] Prospectively registered
21/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
24/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/12/2020	Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
08/063

Study information

Scientific Title
PRAZosin in combination with a serotonin reuptake Inhibitor for patients with Obsessive Compulsive disorder: an open label study

Acronym
PRAZOC

Study objectives
It is hypothesised that prazosin in combination with a Serotonin Reuptake Inhibitor (SRI) might possess an anti-obsessive compulsive disorder (OCD) modulating effect by raising dopamine (DA) levels in the synaptic cleft in the prefrontal cortex and inhibiting extracellular DA concentrations in the nucleus accumbens

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee of the Academic Medical Centre Amsterdam in December 2008

Study design
Open label cohort study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Obsessive compulsive disorder

Interventions
1. Prazosin 5-20 mg/day for 12 weeks in addition to ongoing treatment with SRI
2. The total duration of follow up will be 12 weeks (i.e. no follow up beyond the end of the intervention)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prazosin

Primary outcome(s)
1. Decrease in Y-BOCS score
2. Measured at baseline, 2, 4, 6, 8, 10 and 12 weeks

Key secondary outcome(s))
1. Clinical Global Impression (CGI)
2. Hamilton Depression Rating Scale (HDRS)
3. All outcomes measured at baseline, 2, 4, 6, 8, 10 and 12 weeks

Completion date
01/08/2010

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. Yale-Brown Obsessive Compulsive Scale (Y-BOCS) score (two consecutive measurements within two weeks)
2.1. > 16 if obsessions and compulsions
2.2. > 10 if only obsessions
2.3. > 10 if only compulsions
3. Therapy resistance, defined as not having responded to at least 1 previous treatment with an SRI at maximum dose and duration
4. Male and female, aged between 18-70 years
5. Female patients of childbearing potential must have a negative pregnancy test and use a reliable method of contraception
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Key exclusion criteria
1. Presence of any of the following DSM IV conditions:
1.1. Major depression (with a Hamilton Depression Rating Scale [HDRS] > 15, [17 item])
1.2. Bipolar disorder
1.3. Schizophrenia or any other psychotic condition, tic disorder, substance related disorder during the past 6 months
1.4. Epilepsy
1.5. 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, glaucoma, myocardial infarction within the past year, or micturition abnormalities
3. Patients at risk for suicide

4. Multiple serious drug allergies or known allergy for the trial compounds
5. Use of antipsychotics during 6 months before the screening visit
6. Use of any other psychotropic drug during 6 months before the screening visit
7. Cognitive and behavioural treatment 3 months prior to the screening visit
8. Use of drugs that interact with prazosin: diuretic or other antihypertensive agents (which can cause an additive hypotensive effect)
9. Regular use of alcohol

Date of first enrolment
01/03/2010

Date of final enrolment
01/08/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

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	results	01/02/2016	29/12/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes