ISRCTN61562706 https://doi.org/10.1186/ISRCTN61562706

PRAZosin for patients with Obsessive Compulsive disorder

Submission date	Recruitment status
21/03/2010	No longer recruiting
Registration date	**Overall study status**
24/05/2011	Completed
Last Edited	**Condition category**
29/12/2020	Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Damiaan Denys

Contact details
Academic Medical Centre
Psychiatry
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 891 0602
d.denys@amc.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 measure
1. Decrease in Y-BOCS score
2. Measured at baseline, 2, 4, 6, 8, 10 and 12 weeks

Secondary outcome measures
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

Overall study start date
01/03/2010

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
10

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)

Sponsor details
Psychiatry Department
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ
+31 (0)20 891 3602
m.figee@amc.nl

Sponsor type
Hospital/treatment centre

Website
http://www.amcpsychiatrie.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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