Clinical Trial Details (PDF Generation Date :- Wed, 10 Aug 2022 16:09:35 GMT)

CTRI Number	CTRI/2020/01/022890 [Registered on: 21/01/2020] - **Trial Registered Prospectively**
Last Modified On	07/01/2020
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Comparison of drugs, Fluvoxamine ans Sertraline in patients with OCD in terms of efficacy and effect on neuro-psychological functions.
Scientific Title of Study	Effectiveness of Fluvoxamine and Sertraline on Neuropsychological functions in patients with Obsessive Compulsive Disorder

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Government Medical College and Hospital, Chandigarh

Primary Sponsor

Primary Sponsor Details	
Name	Government Medical College and Hospital Chandigarh
Address	Government Medical College and Hospital, Chandigarh, sECTOR 32, Pin Code: 160030
Type of Sponsor	Government medical college

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Jasmine Brar	Government Medical College and Hospital, Chandigarh	Department of Psychiatry, Government Medical College and Hospital, Chandigarh Chandigarh CHANDIGARH	7009422946 jasminebrar2014@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
GMCH ETHICAL COMMITTEE	Approved	26/12/2018	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Obsessive-compulsive disorder

Intervention / Comparator Agent

Type	Name	Details
Intervention	Fluvoxamine and Sertraline	Selective serotonin reuptake inhibitors
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	55.00 Year(s)
Gender	Both
Details	1. Diagnosis of OCD as per Diagnostic and Statistical Manual of Mental Disorders-5 2. Treatment-naïve patients 3. Those consenting to participate 4. Age group of 18-55 years 5. Any gender

Exclusion Criteria

Exclusion Criteria	
Details	1. Depression, anxiety or any other psychiatric illness of diagnosable severity 2. Co-morbid intellectual disability 3. Co-morbid neurological disorder, organic brain syndrome, dementia, or epilepsy 4. Co-morbid substance dependence except caffeine and nicotine 5. Subjects with high, active suicidal risk

	6. Subjects with severe medical, surgical or any other condition in which these medications are contraindicated 7. Pregnant and lactating females 8. Subjects who received ECT anytime during preceding three months

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	On-site computer system
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
1. To study severity of illness, neuropsychological functions and quality of life in patients with obsessive compulsive disorder. 2. To study the effect of fluvoxamine and sertraline on severity of illness, neuropsychological functions and quality of life in patients with obsessive compulsive disorder.	Baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 12 weeks

Secondary Outcome

Outcome	Timepoints
1. To study the association of socio demographic and clinical variables with severity of illness, neuropsychological functions and quality of life in patients with obsessive compulsive disorder. 2. To compare effects of fluvoxamine and sertraline on above cited parameters.	Baseline, 2 weeks, 4 weeks, 6 weeks, 8 weeks, 12 weeks

Target Sample Size	**Total Sample Size=**50 **Sample Size from India=**50 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	21/01/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NA
Brief Summary	50 patients of OCD will be inducted for the study. Using computer based random number tables, patient will be allocated in Fluvoxamine or Sertraline drug groups. Neuropsychological testing will be done at baseline and at 12 weeks, along with other parameters according to aims and objectives of the study.