Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Nov 2026

Evaluation of Ketamine Hydrochloride’s Effect on Symptom Characteristics and Neuronal Networks Organization in Patients with Obsessive Compulsive Disorder: A Randomized, Double-Blinded, Placebo-Controlled Clinical Trial

Protocol summary

Study aim
Evaluation's of Ketamine hydrochloride effect on symptoms of obsessive-compulsive disorder

Design
Clinical trial with control group, parallel allocation, double-blind, randomized, phase 3 on 60 patients.

Settings and conduct
Jami Neuropsychiatry Clinic National Library of Brain Mapping

Participants/Inclusion and exclusion criteria
Inclusion Criteria: - Definitive diagnosis of obsessive-compulsive disorder - Lack of sufficient response to one standard treatment with enough dose and duration - Y-BOCS Score equal or more than 25 - Being in The age range of 18-40 - IQ level more than 80 based on Wechsler Adult Intelligence Scale - Signing written informed consent Non-Inclusion Criteria - Pregnancy, lactation or the imminent possibility of either of these cases or use of birth control methods for female subjects (these items will be assessed by the validated urine tests) -Past or current drug/alcohol abuse or dependence (these items will be assessed by the urine toxicology tests) - Past history or current existence of neurological diseases (seizures, epilepsy syndromes, history of trauma, stroke, loss of consciousness) and other severe internal and surgical disorders - Presence of any contraindication to MRI scanning

Intervention groups
Ketamine Hydrochloride Group Placebo Group

Main outcome variables
Symptom (Obsession and Compulsions) Severity Based on Yale Brown Obsessive Compulsive Disorder Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140120016280N5**
Registration date: **2021-05-18, 1400/02/28**
Registration timing: **prospective**

Last update: **2021-05-18, 1400/02/28**
Update count: **0**

Registration date
2021-05-18, 1400/02/28

Registrant information

Name
Mahmoudreza Hadjighassem

Name of organization / entity
TUMS

Country
Iran (Islamic Republic of)

Phone
+98 218899111823

Email address
mhadjighassem@tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-23, 1400/05/01

Expected recruitment end date
2023-03-11, 1401/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of Ketamine Hydrochloride’s Effect on Symptom Characteristics and Neuronal Networks Organization in Patients with Obsessive Compulsive Disorder: A Randomized, Double-Blinded, Placebo-Controlled Clinical Trial

Public title
Evaluation of Ketamine Hydrochloride's Effect in Obsessive-Compulsive Disorde

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of obsessive-compulsive disorder based on the psychiatrist assessment and its confirmation according to SCID-5 (Structured-Clinical Interview for DSM5) by the clinical psychologist. Y-BOCS Score equal or more than 25 for obsessions and compulsions Lack of sufficient response to one period of standard treatment with enough dose and duration (less than 25 percent reduction in symptom severity) Being in the age range of 18-40 IQ level more than 80 Signing written informed consent

Exclusion criteria:
Subjects with major depressive disorder, bipolar disorder, personality disorder, and schizophrenia in a way that questions the diagnose of obsessive-compulsive disorder. Pregnancy, lactation or the imminent possibility of either of these cases or use of birth control methods for female subjects (these items will be assessed by the validated urine tests) Past or current substance/alcohol abuse or dependence Past history or current existence of neurological diseases (seizures, epilepsy syndromes, history of trauma, stroke, loss of consciousness) and other severe internal and surgical disorders Presence of any contraindication to MRI scanning, including metal implants or claustrophobia. Metal implants, pacemaker, other metal (e.g. shrapnel or surgical prostheses) or paramagnetic objects contained within the body which may present a risk to the subject or interfere with the MR scan, as determined in consultation with a neuroradiologist and according to the guidelines set forth in the following reference book commonly used by the neuroradiologists:"Guide to MR procedures and metallic objects", F. G.

Age
From **18 years** old to **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each participant will be assessed by functional neuroimaging before and after the Ketamine/Placebo Administration.

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization process will be done using permuted block randomization with blocks in size 15. Regarding determined sample size 60, quadratic blocks will be produced using the online website: (www.sealedenvelope) .com. Unique code will be used to apply the allocation concealment to drug boxes, and the code will also be generated by the software. As each individual enters the study based on the sequence generated, the drug box in which the code in question is assigned will be assigned to the individual.

Blinding (investigator's opinion)
Double blinded

Blinding description
Since the current study will be performed within the neuropsychiatry context and the probability of bias formation and placebo effects are considerable, the subjects and the main investigator that is assessor and also the author of the manuscript would be held blinded. such a way that, the primary neuro-psychological assessments will be executed by the trained clinical psychologist. Staff responsible for preparation of trial medications and randomization process were not further involved in the study. Ketamine / placebo injections are also given by an anesthesiologist who is unaware of the type of allocation (medication / placebo). The patient will also be informed during the registration process that he or she is receiving medication or placebo, and if he or she consents and participates in the plan, will be kept blind to the type of allocation at the time of the ketamine / placebo injection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic Committee of Tehran University of Medical Sciences

Street address
6th floor of the Central Building of Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.083

Health conditions studied

1

Description of health condition studied
Obsessive Compulsive Disorder
ICD-10 code
F42
ICD-10 code description
Obsessive-compulsive disorder

Primary outcomes

1

Description
Symptom (Obsession and Compulsions) Severity Based on Yale Brown Obsessive Compulsive Disorder Scale
Timepoint
Assessment of Severity and pattern of symptoms : at the beginning of study and before the beginning of intervention, 3 days after intervention and then 10 days after intervention.
Method of measurement
Validated Yale Brown Obsessive Compulsive Disorder Scale

Secondary outcomes

1

Description
Functional organization of Large-Scale Brain Networks
Timepoint
72 hours before intervention, and then 72 hours after intervention and 10 days after intervention
Method of measurement
Functional Magnetic Resonance Imaging

Intervention groups

1

Description
Intervention group: This group, which includes subjects diagnosed with obsessive-compulsive disorder, receives injectable ketamine hydrochloride as an intravenous infusion at a dose of 0.5 mg per kg. Ketamine, a non-competitive glutamate receptor antagonist, has recently been approved for anesthesia and used to treat major depressive disorder. Ketamine blocks the effects of persistent, elevated levels of glutamate, which can cause neuronal dysfunction. In addition, memantine provides the conditions for increased expression of the N-methyl di-aspartate receptor gene, which causes glutamate to act at higher concentrations and, in fact, increases the threshold. Ketamine has also been shown to be receptive to gamma-aminobutyric acid, benzodiazepine, dopamine, adrenergic, histamine, glycine, and voltage-gated calcium, sodium, or potassium channels.
Category
Treatment - Drugs

2

Description
Control group: This group, which includes subjects with a diagnosis of obsessive-compulsive disorder, will receive placebo of Ketamine (normal saline), based on the standard protocol for ketamine injection.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Jami Neuropsychiatry Clinic
Full name of responsible person
Dr. Mohammad Arbabi
Street address
Darabnia Alley, Mina Square, Mirdamad Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1333715914
Phone
+98 21 2292 6519
Email
marbabid@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
Street address
Sixth Floor, Central Organization of Tehran University of Medical Science, Qods Street
City
Tehran
Province
Tehran
Postal code
3439123900
Phone
+98 21 8889 3978
Email
tums_edu@tums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Mahmoudreza Hadjighassem
Position
University Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
87, Third floor, Building No.2, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417755469
Phone
+98 02143052000 , +98 02188991102
Email
mhadjighassem@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mahmoudreza Hadjighassem
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Neuroscience
Street address
87, Third floor, Building No.2, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417755469
Phone
+98 02143052000 , +98 02188991102
Fax
+98 21 8899 1117
Email
mhadjighassem@tums.ac.ir
Web page address
http://satim.tums.ac.ir/fa

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Lida Shafaghi
Position
PhD Student
Latest degree
Medical doctor
Other areas of specialty/work
Neuroscience
Street address
87, Third floor, Building No.2, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417755469
Phone
+98 02143052000 , +98 02188991102
Email
lshafaghi@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to

make this available

Title and more details about the data/document

Information of the main (primary outcome) and the secondary outcomes like neuronal networks reorganization outcome could be shared.

When the data will become available and for how long

6 months after publication of results

To whom data/document is available

Research data will be available for the researchers of universities and scientific institutes and also relevant investigators of the industries.

Under which criteria data/document could be used

The data will be available, when the samples are taken out, all the stages of the project are completed and finalized, and the results are published.

From where data/document is obtainable

1. Dr Mahmoudreza Hdjighassem First Address: Neuroscience Group, Reihaneh Department, Keshavarz BLVD, Imam Khomeini Hospital Complex. Tehran. Second Address: 87, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran. Cell Phone Number: 09126779102 Faculty Phone Number: 02143052000 Fax Number: 02188991117 Email Address: mhadjighassem@tums.ac.ir 2. Lida Shafaghi Address: 87, School of Advanced Technologies in Medicine, Italia st, Keshavarz blv. Tehran. Cell Phone Number: 09123832340 Fcaulty Number: 0214305200 Email Address: Lidashafaghi@gmail.com

What processes are involved for a request to access data/document

In order to receive the information, firstly the applicants send the formal application to the correspondent of the present proposal, Dr. Hadjighassem (Associate Professor of the Department of Neuroscience and Addiction studies, School of Advanced Technologies in Medicine) and then they will be informed of the details of the data reception (including timing-that will be tried to be within the shortest possible interval- and the way of the addressing the available data like email or in person.

Comments