Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Study the effectiveness of omega 3 fatty acid as adjuvant treatment on depression, aggression and poor impuls control in hospitalized patients of borderline personality disorder

Protocol summary

Study aim
Study the effectiveness of omega 3 fatty acid on depression, aggression and poor impuls control in patients of borderline personality disorder hospitalized in Razi psychiatric hospital.

Design
Clinical trial, control and intervention group, factorial, two blinded, accidental, phase 3 on 46 patient. The software will use for randomization.

Settings and conduct
All patients with borderline personality disorder are hospitalized in Razi Psychiatric hospital who have the criteria for entering the study will be divided into two intervention and control groups by web software, and for both group of patients DBT psychotherapy will be performed and they will receive olanzapine ranging from 5 to 15 mg . The intervention group wiil also be given a 2 gram omega 3 capsule daily for 6 weeks. All patients will be filed at the beginning of study and end of week 12 Hamilton depression questionnaires, bass and perry aggression and barat impulsiveness and the person who will review the participants in terms of the criteria of entering the study and the person who will attend the group will be different.

Participants/Inclusion and exclusion criteria
Definitive diagnosis of borderline personality disorder based on DSM V, Age range between 18 till 60 years old, Disorder leads to referral for treatment and hospitalization, IQ is higher than 70, Patient and patients price have conscious consent to participate in the study. Having metabolic disorder, having extra pyramidal symptoms

Intervention groups
Control group includes patients with borderline personality disorder who will be treated with olonzapine and psychotherapy. Intervention group includes patients with borderline personality disorder who will be treated with olanzapine, omega 3 and psychotherapy.

Main outcome variables
depression, aggression, poor impulse control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210531051453N1**
Registration date: **2021-07-30, 1400/05/08**
Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**
Update count: **0**

Registration date
2021-07-30, 1400/05/08

Registrant information

Name
Ensieh Sadri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4405 7355

Email address
sadri.ensieh@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-01, 1400/05/10

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study the effectiveness of omega 3 fatty acid as adjuvant treatment on depression, aggression and poor impuls control in hospitalized patients of borderline personality disorder

Public title
Effect of omega 3 fatty acid in borderline personality disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of borderline personality disorder based on DSM V Age range between 18 till 60 years old Disorder leads to referral for treatment and hospitalization IQ is higher than 70 Patient and patients price have conscious consent to participate in the study
Exclusion criteria:
Having psychological disorders except substance abuse disorder Having diabetes, metabolic disorders, serious medical or nourological diseases Having extrapyramidal symptoms such as hands tremor, mouth watering, neck dystonia, rigidity and akathisia Pregnancy and breastfeeding
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **23**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to fix some possible tours in this study, simple coincidence will be observed. In this study, to randomly allocate people to two groups, first using software under the web https://www.Randomization.com a random sequence of number will be created. Also cases such as the person who will create sequence, the person who will check the participants in terms of entry and exit criteria and enroll them in the study, and the person who will assign the participants to the groups are separated from each other.
Blinding (investigator's opinion)
Double blinded
Blinding description
The design of this study will take place in terms of blindness. This type of design is so that the people studied are not aware of the type of study and the evaluation is not aware of the intervention in every patient. The purpose of this type of design is to prevent the appearance of the observers net. This tour means that the results observed from the plane are affected by the attitude and behavior of the patient or doctor. So the design of this study will be done in a way to minimize possible nets and results closer to reality.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of university of social welfare and rehabilitation sciences
Street address
No 17, South Ebrahimi Ave, East Ferdos Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1481958465
Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
IR.USWR.REC.1398.208

Health conditions studied

1

Description of health condition studied
Borderline personality disorder
ICD-10 code
F60.3
ICD-10 code description
Borderline personality disorder

Primary outcomes

1

Description
Depression
Timepoint
At the begining of study and 12 weeks after study
Method of measurement
Depression based on Hamilton scale

2

Description
impulse control
Timepoint
At the begining of study and 12 weeks after study
Method of measurement
impulse control based on Barratt scale

3

Description
aggression
Timepoint
At the begining of study and 12 weeks after study
Method of measurement
Aggression based on Bus and Perry scale

Secondary outcomes

empty

Intervention groups

1

Description
"Intervention group": Olanzapine is an atypic antipsychotic drug with C17H20N4S chemical formulation and tino benzodiazepine derivatives with half life of 21 to 54 hours and has liver metabolism that can inhibit the attraction of serotonin and dopamine at the end of presynapsis nervous system that can reduce aggression and to get better mood. This drug will be used with the dose of 5 to 15 mg per day according to the patient's response for 6 weeks and the drug used by Abidi pharmaceutical company, Omega 3 drug is a long chain fatty acid means an 18 carbonic chain with 3 double transplant on 9, 12 and 15' s carbons. That according to the hypothesis of reducing Omega 3 fatty acids in the membrane of neurons of borderline personality disorder, this drug will be used with the dose of 2 grams a day for 6 week and the drug used by Actover pharmaceutical company. Currently, the only approved treatment for borderline personality disorder is psychotherapy and this treatment is now the most effective treatment for this disorder.Therapists use behavioral therapy to control patient's momentum and anger explosions and to reduce their sensitivity to criticism and expulsion, and through social skills training, the patient is helped to see the impact of their actions on other an their inter individual behavior. Improve Dialectical Behavioral Therapy (DBT),which is the most common type of psychotherapy used in this patient is especially used in patient who have attempted suicide or self esteem and give better control of momentum in patients for 4 weeks and every week for one hour in the psycotherapic clinic in Razi Psychiatric hospital will be performed by final year Psychiatric resident.
Category
Treatment - Drugs

2

Description
"Control group:" Olanzapine is an atypic antipsychotic drug that can reduce aggression and to get better mood by impact on serotonin and dopamin. This drug will be used with the dose of 5 to 15 mg per day according to the patient's response for 6 weeks and the drug used by Abidi pharmaceutical company, According that the only approved treatment for borderline personality disorder is psychotherapy, Dialectical Behavioral Therapy (DBT), the most common type of psychotherapy will be used in theses patients for 4 weeks and every week for one hour in the psycotherapic clinic in Razi Psychiatric hospital will be performed by final year Psychiatric resident.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi psychiatric hospital
Full name of responsible person
Ensieh Sadri
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Taghiabad Blvd, Rey Town
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1866958891
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Razi.pr@uswr.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
Dr Mohammad Reza Khodaei
Street address
Koodakyar Ave, Vekenjak Blvd, Tehran
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1985713871
Phone
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Email
Pr@uswr.ac.ir
Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Ensieh Sadri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

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Person responsible for scientific inquiries

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Position
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available