Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of gene expression pattern in blood sample of depressed patients treated with fluoxetine and cognitive-behavioral therapy

Protocol summary

Study aim
Comparison of gene expression and Brain-derived neurotrophic factor in patients with major depressive disorder treated with fluoxetine and cognitive-behavioral therapy.

Design
The type of study is a randomized clinical trial on the one hand R software will be used for randomization. Sample size: 40 people Patients will be treated in one of two groups: medication and behavior.

Settings and conduct
The research community consists of patients with major depressive disorder who refer to Zare Psychiatric Hospital and the private ward of Sari. Blood samples are taken from patients before and after the intervention and examined for BDNF protein and gene expression.

Participants/Inclusion and exclusion criteria
inclusion criteria: 1-Diagnosis of major depressive disorder 2-pass school grade above 9 3Having at least physical and cognitive ability 4-Lack of psychosis is a serious thought that hurts yourself and others. 5.Failure to receive other psychological treatment at the same time exclusion criteria: 1-Acute psychiatric disorders according to the psychiatrist. 2-The occurrence of serious and restrictive medical diseases. 3.Age range between 18-55 years. 4.Taking other psychotherapeutic drugs.

Intervention groups
Intervention group: Patients with major depressive disorder who are treated with cognitive-behavioral therapy for 12 sessions. In this treatment model, patients with major depression are treated based on their mentality and behavior and various problems ranging from anxiety and depression to a variety of personality disorders. Control group: Fluoxetine treatment group that receives 20 mg of the drug daily for 3 months.Medication therapy is an accepted method by which cognitive-behavioral therapy is compared.

Main outcome variables
Clinical examination of patients Age of onset of the disease The duration of the disease gene expression BDNF protein

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190710044171N1**
Registration date: **2020-09-08, 1399/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-08, 1399/06/18**
Update count: **0**

Registration date
2020-09-08, 1399/06/18

Registrant information

Name
Hossein Ghalehnoei

Name of organization / entity
Mazandaran university of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 11 3334 9337

Email address
hossein.ghalehnoei58@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20

Expected recruitment end date
2020-11-10, 1399/08/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of gene expression pattern in blood sample of depressed patients treated with fluoxetine and cognitive-behavioral therapy

Public title

comparison gene expression pattern in blood sample of patients with major depressive disorder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of major depression Range 18-55 years Graduated from middle school Having minimum physical and cognitive abilities to participate in intervention sessions Lack of psychosis and hurting oneself and others Not receiving any other psychological treatment at the same time

Exclusion criteria:

Acute psychiatric disorders according to the psychiatrist Having a serious medical condition and limiting Taking intervening drugs

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **2**

One sample is taken before the intervention and one sample is taken after the intervention.

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with MDD disorder are identified by a physician based on the DSM-V criteria. The degree of depression of patients is determined by self-assessment based on the Beck questionnaire. Patients are randomly divided into two groups according to Graphpad online software: CBT (intervention) therapies are divided.

Blinding (investigator's opinion)

Single blinded

Blinding description

Cognitive-behavioral group therapy is the study of the blind study group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee Mazandaran of medical sciences

Street address

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences-Moallem Square-Moallem Street-Sari-Iran.

City

sari

Province

Mazandaran

Postal code

4817844718

Approval date

2019-08-07, 1398/05/16

Ethics committee reference number

IR.MAZUMS.REC.1398.759

Health conditions studied

1

Description of health condition studied

major depressive disorder

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

change of gene in trial

Timepoint

evaluation of change in gene after 6 weeks treatment

Method of measurement

gene description

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group receiving 12 sessions of cognitive-behavioral therapy is a group that psychotherapists use to educate people and change their feelings and behaviors through their thought patterns and beliefs. Each session lasts 90 minutes. Control

group: Drug therapy group in which patients take 20 mg of fluoxetine daily for 3 months.

Category

Other

2

Description

Control group: Control group: In the drug therapy group, patients receive 20 mg of fluoxetine daily for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Zare Hospital

Full name of responsible person

Mehdi Pourasghar

Street address

3 Km of Sari Neka Road Sari Iran

City

Sari

Province

Mazandaran

Postal code

33272743

Phone

+98 11 3328 3889

Fax

+98 11 3328 5109

Email

me_pourasghar@yahoo.com

Web page address

https://fa.irct.ir/user/trial/41601/update/recruitment_center

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran universit of medical sciences

Full name of responsible person

Dr Majid saeedi

Street address

Medical biotechnology department school of advanced in technology farah abad av sari town

City

Sari

Province

Mazandaran

Postal code

4814918431

Phone

+98 11 3334 9337

Email

hossein.ghalehnoei58@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran universit 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

Mazandaran university of medical sciences

Full name of responsible person

Hossein Ghalehnoei

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

Street address

Department of Medical Biotechnology school of medicine Payambar Azam Academic complex Farah Abad Boulevard Sari Town

City

Sari

Province

Mazandaran

Postal code

4814918431

Phone

+98 11 3334 9337

Fax

Email

hossein.ghalehnoei58@gmail.com

Web page address

https://fa.irct.ir/user/trial/41601/update/public_queries_contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran university of medical sciences

Full name of responsible person

Hossein ghalehnoei

Position

Assistant professor

Latest degree
Ph.D.
Other areas of specialty/work
Molecular medicine
Street address
Medical biotechnology depatrment-school of advanced in technology-farah abad ave-sari- iran
City
Sari
Province
Mazandaran
Postal code
۴۸۱۴۹۱۸۴۳۱
Phone
+98 11 3334 9337
Email
hossein.ghalehnoei58@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Mazandaran universit of medical sciences
Full name of responsible person
Hossein ghalehnoei
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Molecular medicine
Street address
Medical biotechnology department-school of advanced in technology-farah abad av .,sari town
City
Sari
Province
Mazandaran
Postal code
4814918431
Phone
+98 11 3334 9337
Email
hossein.ghalehnoei58@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available