

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation the response rate in major depressive disorder after taking sertraline as a predictive factor base on motor cortex magnetic brain stimulation.

Protocol summary

Study aim

Evaluation the response rate in major depressive disorder after taking sertraline as a predictive factor base on motor cortex brain stimulation.

Design

Clinical trial :based on community and practical :phase 2 on 48 patients

Settings and conduct

Depressed patients have their Motor Evoked Potential measured and re-measured after a dose of sertralin 2 hours later and then compared.

Participants/Inclusion and exclusion criteria

inclusion :evaluation major depressive disorder Psychiatrist or Hamilton question between 18-65 Age question provided by the Having informed satisfaction and motivation to cooperate and participate in completing the researcher No history of psychiatrist medication use in last two week exclusion :If a person has a specific acute neurological disorder at the same time

Intervention groups

Patients are diagnosed with major depressive disorder and their MEP is measured and then they take a dose of sertraline and then MEP is measured again after 2 hours and then stimulates threshold is compared before and after sertraline.

Main outcome variables

Motor evoked potential

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100119003106N44**

Registration date: **2023-02-16, 1401/11/27**

Registration timing: **retrospective**

Last update: **2023-02-16, 1401/11/27**

Update count: **0**

Registration date

2023-02-16, 1401/11/27

Registrant information

Name

Farshad Hashemian

Name of organization / entity

Pharmaceutical Sciences Branch, Islamic Azad University (IAU)

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the response rate in major depressive disorder after taking sertraline as a predictive factor base on motor cortex magnetic brain stimulation.

Public title

Evaluation the response rate in major depressive

disorder after taking Sertraline as a predictive factor base on motor cortex magnetic brain stimulation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

evaluation major depressive disorder Psychiatrist or Hamilton 24 question Age between 18-65 question provided by the Having informed satisfaction and motivation to cooperate and participate in completing the researcher No history of psychiatrist medication use in last two week

Exclusion criteria:

If a person has a specific acute neurological/ psychological disorder at the same time

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad university of Tehran medical sciences

Street address

No. 99, Yakhchal Street, Gholhak Dr. Shariati St.

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Province

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Postal code

1441933111

Approval date

2022-02-28, 1400/12/09

Ethics committee reference number

IR.IAU.TMU.REC.1400.325

Health conditions studied

1

Description of health condition studied

The effect of sertraline in major depressive disorder

ICD-10 code

F32

ICD-10 code description

Major depressive disorder, single episode

Primary outcomes

1

Description

Determining the Motor evoked potential of patients through transcranial magnetic stimulation

Timepoint

Before taking sertraline and 2 hours after taking sertraline

Method of measurement

Comparison of Motor evoked potential of patients before and after taking sertraline

Secondary outcomes

1

Description

Hamilton and Beck depression questionnaire

Timepoint

Before taking sertraline and after taking sertraline

Method of measurement

Comparison of Hamilton and beck depression score of patients before and after taking sertraline

Intervention groups

1

Description

Intervention group :48 patients with major depression in the age group of 18 to 65 years will be selected by a psychiatrist or by using the Hamilton and beck questionnaire and the amount of motor evoked potential will be measured for them before taking the drug.

Category

Treatment - Drugs

2

Description

Control group: including 48 patients with major depression in the age group of 18 to 65 years, confirmed by a psychiatrist and will be selected using the Hamilton and Beck questionnaire, and the amount of motor evoked potential will be measured for them after taking 100 mg of sertraline.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mental health Atie clinic

Full name of responsible person

Dr. Reza Rostami

Street address

No 99 , yasaman alley , yakhchal street ,Gholhak,Dr shariati street ,tehran Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Research Unit of Azad Islamic University of Medical Sciences

Proportion provided by this source

1

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

mahsima moosavandi

Position

Pharmacy student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. farshad Hashemian

Position

Pharm D. Bcps, Professor

Latest degree

Specialist

Other areas of specialty/work

Medical pharmacy

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Person responsible for updating data

Contact

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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

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

Title and more details about the data/document

Evaluation the response rate in major depressive disorder after taking sertraline as a predictive factor base on motor cortex magnetic brain stimulation.

When the data will become available and for how long

Just after the articles publication.

To whom data/document is available

For all investigators.

Under which criteria data/document could be used

No more information.

From where data/document is obtainable

Applicants can refer to the department of clinical pharmacy faculty of pharmacy, Tehran medical science Islamic area university Dr. Hashemian or contact the researcher by sending email to mahsimamoosavandi1@gmail.com or calling 09127834959.

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

the information. Applicant must commit themselves to mention the source. If the request is sent six months after the publication of research information the researcher will send the data to the requesting party by email within a week.

Comments