

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Additive Effect of Botulinum Toxin on Conventional Treatment in Bipolar disorder current episode depression

Protocol summary

Study aim

Additive Effect of Botulinum Toxin on Conventional Treatment in Bipolar disorder, current episode depression

Design

A randomized clinical trial with parallel control group, double blind; Phase 2-3, on 70 patients; randomization is performed by using block randomization.

Settings and conduct

This study is performed in Farshchian Hospital in Hamadan

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with diagnosed bipolar depression based on DSM-5 and MADRS score equal to or more than 7. Exclusion criteria: history of Botox injections in the past year; contraindication to receiving botulinum type A.

Intervention groups

In the intervention group: injection of 48 units in women and 64 units in men Botulinum toxin type A from support brand soluble in 2 cc of normal saline in 8 points glabellar & forehead. Control group: normal saline 9% with a volume equal to the intervention group at 8 points glabellar & forehead.

Main outcome variables

Compare rates of depression before and after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N7**

Registration date: **2021-01-18, 1399/10/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-18, 1399/10/29**

Update count: **0**

Registration date

2021-01-18, 1399/10/29

Registrant information

Name

Mohammad Faryadras

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3428 9706

Email address

m.faryadras@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Additive Effect of Botulinum Toxin on Conventional Treatment in Bipolar disorder current episode depression

Public title

Botulinum type A treatment of depressive episode in bipolar patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diagnosed bipolar depression based on DSM-5 MADRS score equal to or more than 7

Exclusion criteria:
History of Botox injections in the past year.
Contraindication to receiving botulinum type A.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
More than 1 sample in each individual
Number of samples in each individual: **35**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to the intervention and control groups using block randomization. The patients will be randomly assigned to the intervention and control groups using block randomization; arrangement of the randomization process: 1); determining the volume of each block (quadruple blocks) 2); preparing the list of the blocks and assigning a number (between 1 and 6) to each of them 3); choosing random numbers between 1 and 6; 4) defining the treatment assignment list.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and the examining physician will not be aware of the patient's type of drug treatment, so the study will be double-blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

City

Hamadan
Province
Hamadan
Postal code
6517838695

Approval date
1960-05-24, 1339/03/03

Ethics committee reference number
IR.UMSHA.REC.1399.223

Health conditions studied

1

Description of health condition studied

Bipolar II disorder

ICD-10 code

F31.81

ICD-10 code description

Bipolar II disorder

Primary outcomes

1

Description

Depression rate

Timepoint

At the start of intervention- After intervention

Method of measurement

Hamilton Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: injection of 48 units in women and 64 units in men Botulinum toxin type A from support brand soluble in 2 cc of normal saline in 8 points Glabellar & forehead

Category

Treatment - Drugs

2

Description

Control group: normal saline 9% with a volume equal to the intervention group at 8 points Glabellar & forehead

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Hospital
Full name of responsible person
Lila Jahangard
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 1828 5015
Email
Jahangard_Li@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
Street address
Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0717
Email
vc_research@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences
Full name of responsible person
Lila Jahangard
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81182851015
Email
Jahangard_Li@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Lila Jahangard
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan
Province
Hamadan
Postal code
6517838695
Phone
+98 81 1828 5015
Email
Jahangard_Li@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Lila Jahangard
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics

Street address

Farshchian Hospital, Mirzadeh Eshghi Ave.

City

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Province

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6517838695

Phone

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Email

Jahangard_Li@yahoo.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 not a plan to make this available

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