Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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
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Name of organization / entity
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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person
Dr Saeid Bashirian

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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
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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