Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jul 2026

Additive effect of Citicoline on conventional treatment of Bipolar in curent manic episode

Protocol summary

Study aim
Additive effect of Citicoline on conventional treatment of Bipolar in curent manic episode

Design
35patient diagnosed with Bipolar Disorder in manic phase treated treated with one dose of 250 mg/kg of Citicolin for 2 weeks and 35 patients in the control group that were receiving placebo. mood disorders was evaluated by YMRS. by the way both groups were treated with the standard treatment of Bipolar Disorder.

Settings and conduct
This clinical trial will be done in the psychiatry ward of Sina Farshchian hospital 35 patient diagnosed with bipolar disorder in manic phase treated with one dose of 250 mg/kg of Citicolin for 2 weeks and 35 patients in the control group that were receiving placebo mood disorders was evaluated by YMRS. by the way both groups were treated with the standard treatment of Bipolar Disorder. and the researcher does not know that which patient is receiving Citicolin and which is receiving placebo,and in this research one of psychiatric doctor will randomly choose which 35 patients receive Citicolin and which other 35 patients were to receive placebo treatment.

Participants/Inclusion and exclusion criteria
Young Mania Rating Scale greater than or equal to 20 Consent agreement to participate in the study Hospital Admission due to psychiatrist opinion Age greater than or equal to 16

Intervention groups
35 patient diagnosed with Bipolar Disorder in manic phase treated with one dose of 250 mg/kg of Citicolin for 2 weeks and 35 patients in the control group that were receiving placebo.

Main outcome variables
Young Mania Rating Scale is measured at admission,1 and 2 weeks after intervention in mania phase of Bipolar Disorder patients and mood changes in the 2 groups receiving Citicolin and placebo are examined

General information

Reason for update

Acronym
Citicolin in Bipolar Disorder

IRCT registration information
IRCT registration number: **IRCT20090304001743N17**
Registration date: **2020-08-02, 1399/05/12**
Registration timing: **prospective**

Last update: **2020-08-02, 1399/05/12**
Update count: **0**

Registration date
2020-08-02, 1399/05/12

Registrant information

Name
Mohammad Haghighi

Name of organization / entity
Research Center for Behavioral Disorders and Substance Abuse, Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Additive effect of Citicoline on conventional treatment of Bipolar in curent manic episode

Public title
Effect of Citicoline in Bipolar Disorder in current manic epiode

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Young Mania Rating Scale greater than or equal to 20 Consent agreement to participate in the study Hospital Admission due to psychiatrist opinion Age greater than or equal to 16
Exclusion criteria:
Psychiatric disorders except Bipolar 1 Disorder Not to have medical disease Citicolin Contraindication

Age
From **16 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Randomized

Randomization description
we use random blocks of 4 ,utilizing 4 sheets of paper. then , we write number "1 " on 2 sheets and number" 2" on two other sheets.in this context ,"1 "means intervention and " 2 " means comparison, we combine those sheets and place them in the table drawer .each time the patient pulls out one of the sheets randomly , according as which numbler 1 or two is pulled out ,it wil be assigned to intervention group or comparison group.Also it is wise to say that the sheets that are pulled out ,will not be returned to the drawer until all the 4 sheets have been pulled out ,so after pulling out the last sheet all the sheets will be returned to the drawer and this process will be done for the next four patients until we get to the number of samples needed ,And in this researcher the drug and placebo are not notified by the researcher and the patient, So the study will be done double blind.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, placebo, which is precisely in the form of a drug product, is administered randomly to the patients and explained to the patients that he or she may receive a drug or placebo. Therefore, the patient and the clinical caregiver are not aware of the type of product.The other person other than the investigator is responsible for the preparation of the drug and placebo boxes and the researcher is not aware of it. The investigator of the outcome is also unaware of the type of product.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Fahmideh Bulvar.Mahdieh street
City
Hamadan
Province
Hamadan
Postal code
65178

Approval date
2020-05-09, 1399/02/20

Ethics committee reference number
IR.UMSHA.REC.1399.148

Health conditions studied

1

Description of health condition studied
Bipolar Disorder manic episode

ICD-10 code
F31.2

ICD-10 code description
Bipolar Disorder, current episode manic severe with psychotic features

Primary outcomes

1

Description
The effectiveness of Citicoline on reduction of mania episode in bipolar patients administered by YMRS

Timepoint
Assessment of mania status administered by Young Mania Rating Scale at the first date of hospitalization, and the first and second week of receiving Citicoline

Method of measurement
Young Mania Rating Scale

Secondary outcomes

1

Description
The reduction of mania symptoms
Timepoint
At the start of the study and the first and second week after receiving citicolin
Method of measurement
Young Mania Rating Scale (YMRS)

Intervention groups

1

Description
Intervention group: 35 patients diagnosed with Bipolar Disorder in manic phase will be treated with 250 mg /day of Citicolin wich will be one dose through inter muscular injection . The Young Mania Rating Scale will be filled for the patients at admission,first and second weeks of treatment.The drug Citicolin stimulates the biosynthesis of phospholipids and the decreaseof inflammtion stables the cell member.The Citicolin injection will be prepared from MINOO Pharmaceutical.
Category
Treatment - Drugs

2

Description
Control group: 35 patients diagnosed with Bipolar Disorder in mania phase will receive placebo besides their standard drug treatment, and the Young Mania Rating Scale will be filled for the patients at admission,first and second weeks of treatment.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Sara Rezaee
Street address
Dibaj Street
City
Hamadan
Province
Hamadan
Postal code
65175
Phone
+98 81 3827 1066
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2

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Saeed Bashirian
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s-bashirian@umsha.ac.ir
Grant name
Hamedan University of Medical Sciences
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

Sara Rezaee

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Psychiatrics

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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

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available