

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Impact of clinical pharmacist interventions on the clinical outcome of patients with Bipolar Disorder (BD) in Roozbeh hospital

Protocol summary

Study aim

The results of this study can make a pattern for other clinical pharmacists for working in a psychiatry hospital

Design

Two arm parallel groups including intervention group and control group each consists of 56 patients, without blinding, randomized with Random Permuted Block method

Settings and conduct

The impact of clinical pharmacist interventions on the clinical outcome of patients with Bipolar Disorder (BD) who admitted in Roozbeh hospital will be evaluated during hospital stay , one month and three months after discharge

Participants/Inclusion and exclusion criteria

Patients diagnosed with Bipolar Disorder type 1 based on DSM 5 criteria; Patients older than 18 years of age; Taking at least one antipsychotic or mood stabilizer

Intervention groups

In intervention group, clinical pharmacist interventions and consultations during hospitalization, one month and three months after discharge are conducted and the questionnaires will be filled. In control group, no clinical pharmacist intervention is conducted except for life threatening errors and the questionnaires will be filled during hospitalization, one month and three months after discharge. All patients in this study (including intervention and control groups) will benefit from routine and standard pharmacotherapy program according to the orders of their specialists

Main outcome variables

Medication Appropriateness Index; Depression score; Quality of life; Medication adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210307050613N1**

Registration date: **2021-08-21, 1400/05/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-21, 1400/05/30**

Update count: **0**

Registration date

2021-08-21, 1400/05/30

Registrant information

Name

nazanin gorgzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4436 3885

Email address

nazanin.gz67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-20, 1400/05/29

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of clinical pharmacist interventions on the clinical outcome of patients with Bipolar Disorder (BD) in Roozbeh hospital

Public title

Impact of clinical pharmacist interventions on the clinical outcome of patients with Bipolar Disorder (BD)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with Bipolar Disorder type 1 based on DSM 5 criteria Patients older than 18 Taking at least one antipsychotic or mood stabilizer

Exclusion criteria:

Psychiatric comorbidities including Schizophrenia, Obsessive-Compulsive Disorder, Generalized anxiety Disorder, Panic Disorder Drug or disease induced bipolar disorder Substance abuse (other than nicotine or caffeine) since one year ago

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Institute of Pharmaceutical Sciences of Tehran University of Medical Science

Street address

No 16, Jahad Alley., South Shahrn St

City

Tehran

Province

Tehran

Postal code

1474948185

Approval date

2021-05-03, 1400/02/13

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.029

Health conditions studied

1

Description of health condition studied

Bipolar Disorder type 1

ICD-10 code

F31

ICD-10 code description

Bipolar Disorder

Primary outcomes

1

Description

Medication Appropriateness Index

Timepoint

During hospitalization, one month and three months after discharge

Method of measurement

Medication Appropriateness Index questionnaire

Secondary outcomes

1

Description

Depression score

Timepoint

During hospitalization, one months and three months after discharge

Method of measurement

Beck Depression Inventory questionnaire

2

Description

WHOQOL-BREF (WHO Quality Of Life)

Timepoint

During hospitalization, one month and three months after discharge

Method of measurement

WHO Quality Of Life questionnaire

3

Description

Adherence to treatment plan

Timepoint

During hospital stay, one month and three months after discharge

Method of measurement

Medication Adherence Rating Scale

Intervention groups

1

Description

Intervention group: clinical pharmacist interventions and consultations during hospitalization then one month and

three months after discharge as an outpatient

Category

Treatment - Other

2

Description

Control group: clinical pharmacist interventions and consultations only in life-threatening cases during hospitalization then one month and three months after discharge as an outpatient

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Nazanin Gorgzadeh

Street address

South Kargar

City

Tehran

Province

Tehran

Postal code

13337159140

Phone

+98 21 5541 9151

Fax

+98 21 5541 2756

Email

hosp_roozbeh@tums.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazanin Gorgzadeh

Street address

Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 4436 3885

Email

pharmacy@tums.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Personal

Proportion provided by this source

100

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazanin Gorgzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

South Shahran

City

Tehran

Province

Tehran

Postal code

1474948185

Phone

+98 21 4436 3885

Email

nazanin.gz67@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazanin Gorgzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

South Shahran

City

Tehran

Province

Tehran
Postal code
1474948185
Phone
+98 21 4436 3885
Email
nazanin.gz67@gmail.com

1474948185
Phone
+98 21 4436 3885
Email
nazanin.gz67@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Nazanin Gorgzadeh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
South Shahrān
City
Tehran
Province
Tehran
Postal code

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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