

# 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**

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**Province**

Tehran

**Postal code**

13337159140

**Phone**

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**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**

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1417614411

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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

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South Shahrān

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**Position**

Resident

**Latest degree**

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## 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