

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Comparing the effect of Trazodone and Quetiapine on recovery of sleep disturbances on patients who received methadone maintenance therapy

#### Protocol summary

##### Study aim

Comparing the effect of Trazodone and Quetiapine on recovery of sleep disturbances on patients who received methadone maintenance therapy

##### Design

Clinical trial study, phase 3, randomized, parallel groups, each group 35 patients was designed in the period of 2017-2018

##### Settings and conduct

Patients in Zakerian addiction treatment center (Babol University of Medical Sciences) due to substance use disorder undergo Methadone maintenance therapy and according to the Pittsburgh questionnaire they have sleep disturbance.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing Methadone maintenance treatment who received a total score of over 5 according to the PSQI questionnaire, the substance used by the patient should not interfere with Quetiapine and Trazodone drugs. No-entrance criteria: Unwillingness to participate in the study; Having a previous illness that prohibits prescribing drugs.

##### Intervention groups

Group 1: 35 patients receive Trazodone. Group 2: 30 patients receive Quetiapine

##### Main outcome variables

Sleep quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180527039860N1**

Registration date: **2018-10-07, 1397/07/15**

Registration timing: **retrospective**

Last update: **2018-10-07, 1397/07/15**

Update count: **0**

##### Registration date

2018-10-07, 1397/07/15

##### Registrant information

###### Name

Elham Serajpour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3229 1253

###### Email address

e.serajpour@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-06, 1397/05/15

##### Expected recruitment end date

2018-09-22, 1397/06/31

##### Actual recruitment start date

2018-08-06, 1397/05/15

##### Actual recruitment end date

2018-09-25, 1397/07/03

##### Trial completion date

2018-09-25, 1397/07/03

##### Scientific title

Comparing the effect of Trazodone and Quetiapine on recovery of sleep disturbances on patients who received methadone maintenance therapy

##### Public title

Comparison of the effect of Quetiapine and Trazodone on sleep improvement

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients undergoing Methadone maintenance treatment, who received a total score of over 5 according to the PSQI questionnaire. The substance used by the individual does not interfere with Trazadone and Quetiapine drugs.

**Exclusion criteria:**

Unwillingness to participate in the study. Having a previous illness that prohibits prescribing drugs.

**Age**

No age limit

**Gender**

Male

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **70**

Actual sample size reached: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The randomization method was performed using a random number table. First, numbers from 1 to 70 were randomly generated using SPSS software (statistical packages for social sciences) and top-down one among the numbers associated with Trazodone and Quetiapine.

**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 Babol University of Medical sciences

**Street address**

Babol University of medical sciences, Ganjafrooz street

**City**

Babol

**Province**

Mazandaran

**Postal code**

45745-47176

**Approval date**

2018-03-03, 1396/12/12

**Ethics committee reference number**

MUBABOL.HRI.REC.1396.241

**Health conditions studied**

1

**Description of health condition studied**

Sleep disturbances

**ICD-10 code**

G47.0

**ICD-10 code description**

Disorders of initiating and maintaining sleep [insomnia]

**Primary outcomes**

1

**Description**

Sleep quality

**Timepoint**

End of one month after treatment begins

**Method of measurement**

Pittsburgh sleep quality index

**Secondary outcomes**

1

**Description**

General health

**Timepoint**

End of one month after treatment begins

**Method of measurement**

General health questionnaire

**Intervention groups**

1

**Description**

"Intervention group 1": In male patients with methadone treatment that has been associated with sleep disturbances during treatment with this drug, terazodone tablet from Tehran Chemie and Razak Pharmaceutical company at a dose of 25-100 mg, It is prescribed daily (evening) for one month.

**Category**

Treatment - Drugs

2

**Description**

"Intervention group 2": In male patients with methadone treatment that has been associated with sleep disturbances during treatment with this drug, Quetiapine tablet from Tehran Chemie and Bakhtar Bioshimi Pharmaceutical company at a dose of 25-200 mg, It is prescribed daily (evening) for one month.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Zakerian addiction treatment center

**Full name of responsible person**

Sekine Javadian

**Street address**

Zakerian addiction center, Gele mahale intersection, Babol, Mazandaran

**City**

Babol

**Province**

Mazandaran

**Postal code**

47745-47176

**Phone**

+98 11 3232 2610

**Email**

Javadian1939@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Sekine Javadian

**Street address**

Babol University Of Medical Sciences, Daneshgah square, Ganjafrooz Avenue

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Sekine Javadian

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Sekine Javadian

**Position**

Associate professor

**Latest degree**

Specialist

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## Person responsible for updating data

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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**

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