

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The evaluation of the effect of adding Clonidine to Sertraline in the severity of attachment and suffering from detachment in depression of the post-breakup women.

#### Protocol summary

##### Study aim

The evaluation of the effect of adding Clonidine to Sertraline in the severity of attachment and suffering from detachment in depression of the post-breakup women.

##### Design

90 patients of Razi Hospital psychiatric clinic are included in the study, divided into two 45 patients groups. After 8 weeks follow up, patients will score their severity of attachment and suffering from detachment with visual analog scale. Then the scores of two groups rating from 0 to 100 will compared.

##### Settings and conduct

Patients visited in psychiatric clinic of Razi Hospital will be included in the study. After taking history they will be placed in intervention or control group according to inclusion and exclusion criteria and severity of attachment and suffering from detachment will be measured by visual analog scale. After 2 months of treatment, severity of attachment and suffering from detachment will be remeasured. Scores of both groups will be compared with each other.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Females aging 20-40; The experience of emotional breakup in the last 6 months; informed consent (voluntary participation) Exclusion criteria: Comorbid anxiety disorder, Obsessive compulsive disorder; Personality Disorder, Substance abuse, Psychosis, Bipolar Disorder; Antihypertensive medication; History of Heart disease; Depression due to medical disorder; Egodystonic attachment and dependency; Severe depression with Beck score of 35 and above; Essential turnovers after breakup e.g. divorce

##### Intervention groups

One group will treated with Sertraline 50 mg and the other, with Sertraline 50 mg plus 1/4 Clonidine 0.2 mg

##### Main outcome variables

severity of attachment and suffering from detachment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100105002999N10**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

##### Registration date

2018-06-27, 1397/04/06

##### Registrant information

##### Name

Alireza Farnam

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 5951

##### Email address

farnama@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-08-23, 1397/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The evaluation of the effect of adding Clonidine to Sertraline in the severity of attachment and suffering from detachment in depression of the post-breakup women.

**Public title**  
The evaluation of the effect of adding Clonidine to Sertraline in the severity of attachment and suffering from detachment in depression of the post-breakup women.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Females aging 20-40 The experience of emotional breakup in the last 6 months informed consent(voluntary participation)  
**Exclusion criteria:**  
Comorbid anxiety disorder, Obsessive compulsive disorder Personality Disorder, Substance abuse, Psychosis, Bipolar Disorder Antihypertensive medication History of Heart disease Depression due to medical disorder Egodystonic attachment and dependency Severe depression with Beck score of 35 and above Essential turnovers after breakup e.g. divorce

**Age**  
From **20 years** old to **40 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
simple 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 Tabriz University of Medical Sciences  
**Street address**  
Razi Hospital,El goli Ave.  
**City**  
Tabriz  
**Province**  
East Azarbaijan  
**Postal code**  
5166614766  
**Approval date**  
2018-02-04, 1396/11/15  
**Ethics committee reference number**  
IR.TBZMED.REC.1396.986

## Health conditions studied

**1**  
**Description of health condition studied**  
Depression  
**ICD-10 code**  
F32  
**ICD-10 code description**  
Major depressive disorder, single episode

## Primary outcomes

**1**  
**Description**  
Severity of attachment  
**Timepoint**  
measurement of the severity of attachment at the beginning and 8 weeks after intervention  
**Method of measurement**  
Visual analogue scale

**2**  
**Description**  
Suffering from detachment  
**Timepoint**  
measurement of the suffering from detachment at the beginning and 8 weeks after intervention  
**Method of measurement**  
Visual analogue scale

## Secondary outcomes

empty

## Intervention groups

**1**  
**Description**  
Intervention group: Sertraline 50 milligram orally once daily plus 1/4 Clonidine 0.2 milligram Orally at night  
**Category**  
Treatment - Drugs

## 2

### Description

Control group: Sertraline 50 milligram Orally once daily.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Razi Hospital

**Full name of responsible person**

Azar Heidarzadeh

**Street address**

El goli Ave.

**City**

Tabriz

**Province**

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**Postal code**

5166614766

**Phone**

+98 41 3380 3353

**Fax**

+98 41 3380 3353

**Email**

a.heidarzadeh67@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Abolghasem Jouyban

**Street address**

Golgasht Ave.

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**Phone**

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**Email**

ajouyban@hotmail.com

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

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Azar Heidarzadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Psychiatrics

**Street address**

Razi Hospital, El goli Ave. , Tabriz

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Azar Heidarzadeh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Azar Heidarzadeh

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**Email**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Only outcome information will share including visual analog scores and ages.

**When the data will become available and for how long**

6 months after publication

**To whom data/document is available**

For people working in academic institutions

**Under which criteria data/document could be used**

For research purposes, not for treatment No research data publication

**From where data/document is obtainable**

Azar Heidarzadeh +989141051492

**What processes are involved for a request to access data/document**

Phone contact and to receive documents after 1 week

**Comments**