

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

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El goli Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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Golgasht Ave.

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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

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Razi Hospital, El goli Ave. , Tabriz

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Person responsible for scientific inquiries

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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