Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of therapeutic effect of sertraline and supportive psychotherapy in comparison with placebo in coronary heart disease patients with mild to moderate depression

Protocol summary

Study aim
Determination and comparison of sertraline and supportive treatment and placebo on depression in coronary artery disease patients Comparison of mean depression scores in three treatment groups

Design
In this study, 90 patients with coronary artery disease who are suffering from depression and who have criteria for entering the study are selected. Participants are randomly divided into three groups and each participant will be assigned a code.

Settings and conduct
This study is done in patients with coronary artery disease with depression referring to Ali ibn Abitalib Hospital in Zahedan. After entering the study, patients randomly divided into three groups receiving sertraline, a group receiving psychotherapy and a placebo group. They will be.In the group receiving sertraline, the drug is given to patients with a dose of 50 mg, and within a week it will reach 150 to 200 mg. The placebo group will also use the sertraline placenta. The psychotherapy recipient group will be interviewed and supportive once a week for 6 weeks and 45 minutes each.The homogeneity of the age distribution of patients is assessed in three groups To determine the level of depression in patients, a questionnaire was completed for each patient, and then the level of depression in the first, third and sixth weeks was re-evaluated using the same questionnaire.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Having Heart Disease, Non-use of psychiatric drugs, Mild to moderate depression No other serious medical illness Exclusion criteria: Taking heart medications affecting the mood Serious medical illness

Intervention groups
In this study, the effectiveness of psychotherapy in comparison with sertraline and placebo in the treatment of depression in patients with coronary artery disease is studied.

Main outcome variables
depression level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171105037241N2**
Registration date: **2017-12-26, 1396/10/05**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-26, 1396/10/05**
Update count: **1**

Registration date
2017-12-26, 1396/10/05

Registrant information

Name

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 915 549 2771

Email address
dr.sourizahi58@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-04-21, 1397/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of sertraline and supportive psychotherapy in comparison with placebo in coronary heart disease patients with mild to moderate depression

Public title

Comparison of therapeutic effect of sertraline and supportive psychotherapy in comparison with placebo in coronary heart disease patients with mild to moderate depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

coronary heart disease mild to moderate depression No serious medical illness Non-use of psychiatric drugs

Exclusion criteria:

Heart medications affecting the mood

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Easy and accessible and assigned to groups based on randomly clustered blocks

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants are kept blind to the type of drug they receive

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Zahedan University of Medical Sciences

Street address

DrHesabi Square

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.ZAUMS.REC.1396.158

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

f32.0

ICD-10 code description

F32 Depressive episode In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity. Capacity for enjoyment, interest, and concentration is reduced, and marked tire

2

Description of health condition studied

Mild Depression

ICD-10 code

f32.0

ICD-10 code description

F32.0 Mild depressive episode Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

3

Description of health condition studied

Moderate depression

ICD-10 code

f32.1

ICD-10 code description

F32.1 Moderate depressive episode Four or more of the above symptoms are usually present and the patient is likely to have great difficulty in continuing with ordinary activities.

Primary outcomes

1

Description

Depression level in patients with coronary artery disease

Timepoint

first, third, sixth weeks

Method of measurement

Hamilton Depression Survey Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, cognitive-behavioral interventions are performed to improve depression in patients with coronary artery disease. These interventions will be conducted in seven sessions. Session 1: Patients' experiences with depression in response to the diagnosis of heart disease are presented and discussed in their experimental form.. The purpose of this section is to provide a formulation of the psychological problems of patients. According to the experiences of patients, the goals of the sessions and educational needs are determined, and the participants arrive at an understanding of the cognitive-behavioral therapy program.Significantly, at this time, avoidance of thoughts and feelings associated with the disease may occur at the time, most of which are due to admissions and side effects of the treatment. The second component of the first session is to introduce references to controlled diaphragmatic breathing and gradual muscle relaxation training. A training session is provided for both techniques.Second session: Five next weekly sessions begin with a review of homework and examine any problems that patients have encountered. The second session involves exposure and cognitive therapy. Cognitive therapy is introduced at the second session to allow patients to use this strategy during treatment, as well as during preparation and during exercise training sessions.Although cognitive-behavioral therapy can not recognize the prognosis of an illness, the Imam can help the patient better deal with the disease. How to manage their painful prejudices and assumptions will help patients to improve their quality of life somewhat. .Behavioral activation goals: a) Helping the patient to plan for the weekly without pressure feelings as well as family and work commitments; b) engaging in at least one meaningful activity for the patient for at least 15-20 minutes per day.Patients undergoing treatment are more likely to find a better chance to adapt to the routine of the hospital. Session 5: The main part of Session 5 is the continued prolonged imaginary endeavor, followed by an inference with a cognitive reconstruction of cognitive therapy.For these clients, emphasis on the fifth session focuses on cognitive reconstruction. As a result of this meeting, all users will be encouraged to continue to practice the strategies trained in this program. Session Six: Session Six is the last session of the week. When reviewing the homework, each key component is also reviewed in the treatment plan. Clients are encouraged to continue these strategies until the end of the regimen.The post-treatment period is a basic period of adaptation and an attempt to return to normal before the diagnosis of the disease. Hence, recurrence prevention strategies are provided at session 6. Particularly, the goal of this section is to help the patient to take into account future experiences and challenges that they may encounter, and that the patient is equipped with facilities to overcome these problems.The patient should practice cognitive-behavioral therapy skills to neutralize disastrous thoughts and beliefs and be able to adapt to this uncertainty. The seventh session of this support session will be held one month after the end of the sixth session. The purpose of the study is to investigate the progress of references in the application of the behavioral cognitive skills of the past four weeks.Also, checking if the patient has encountered a new problem, or any obstacle to the implementation of strategies to prevent recurrence.

Category

Behavior

2

Description

Intervention group :Sertraline receiving group: In this group, sertraline tablets are given to patients 50 mg orally once a day and will receive 150 to 200 mg per week.

Category

Treatment - Drugs

3

Description

Control groupIn : the placebo group, the sertraline placebo will also be used, which is used in this study of vitamin C

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-Ebn-Abitaleb hospital

Full name of responsible person

Mohammadislam Sourizahi

Street address

Khalijfars Blvd

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5575

Fax

+98 54 3329 5563

Email

dr.sourizahi58@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Noormohammad Bakhshani
Street address
DrHesabi Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5715
Email
dr.sourizahi58@zaums.ac.ir
Grant name
Thesis cost
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Mohammadislam Sourizahi
Position
psychiatric assistant
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Zahedan, DrHesabi square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5715
Fax
Email
dr.sourizahi58@zaums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohammadislam Sourizahi
Position
psychiatric assistant
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Zahedan, DrHesabi square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5715
Fax
Email
dr.sourizahi58@zaums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Mohammadislam Sourizahi
Position
psychiatric assistant
Latest degree
Medical doctor
Other areas of specialty/work
Psychiatrics
Street address
Zahedan, DrHesabi square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 915 549 2771
Fax
Email
dr.sourizahi58@zaums.ac.ir

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