

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The study of of Escitalopram's effectiveness on treatment of mild to moderate depressive disorder and improvement of quality of life in patients who are undergone coronary artery bypass graft surgery (CABG) - A randomized double blind placebo controlled trial

Protocol summary

Study aim

The study of Escitalopram's effectiveness on treatment of mild to moderate depressive disorder and improvement of quality of life in patients who are undergone coronary artery bypass graft surgery

Design

Clinical trial with control group, double-blind, randomized on 50 patients. Randomization using the software

Settings and conduct

Patients who are undergoing Coronary Artery Bypass Graft surgery in Tehran Heart Center hospital are evaluated with Beck Depression Inventory and Quality of Life questionnaire (Short Form-36) and their demographic characteristics will be registered. BDI scores from 10 to 20 are Confirmed through clinical interview by a psychiatrist. patients are randomly divided into intervention group and control group. The study is blinded from the patients and the researcher. Both groups are treated for 8 weeks. During the second week and the fourth week of the treatment , patients are visited in the clinic in order to investigate side effects of drug. Questionnaires will be completed in the fourth week and the end of treatment (week 8)

Participants/Inclusion and exclusion criteria

inclusion criteria: coronary artery bypass graft surgery ,Age (18-75), Beck Depression Inventory score (10-20), exclusion criteria: Previous history of intolerance to SSRI ,Psychosis or dementia or mental retardation disorder ,Severe liver disease,High risk of postoperative cardiac complications such as bleeding, participating in other trials, History of Bipolar Disorder, Patients who have been treated with escitalopram or an antidepressant during the previous month, Recent alcohol and substances abuse,Pregnancy and lactation

Intervention groups

intervention group: tablet escitalopram 10 mg (Selective

Serotonin Reuptake Inhibitors) and control group : tablet placebo , both drugs produced by Abidi company ,once a day ,one tablet, for 8 weeks

Main outcome variables

Depression: Quality of life

General information

Reason for update

Edit study execution time and sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20140126016374N2**

Registration date: **2020-11-22, 1399/09/02**

Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**

Update count: **3**

Registration date

2020-11-22, 1399/09/02

Registrant information

Name

Mohammad Reza Khodaie Ardakani

Name of organization / entity

University of Social Welfare & Rehabilitation Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 3340 1604

Email address

kh.ardakani@uswr.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

2020-12-21, 1399/10/01

Actual recruitment end date

2021-06-21, 1400/03/31

Trial completion date

2021-06-21, 1400/03/31

Scientific title

The study of of Escitalopram's effectiveness on treatment of mild to moderate depressive disorder and improvement of quality of life in patients who are undergone coronary artery bypass graft surgery (CABG) – A randomized double blind placebo controlled trial

Public title

Escitalopram's effectiveness on treatment of depressive disorder and improvement of quality of life in patients who are undergone coronary artery bypass graft surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

coronary artery bypass graft surgery Age >18 (18-75) patient with beck depression inventory score 10-20

Exclusion criteria:

Previous history of intolerance to serotonin reuptake inhibitor antidepressants Psychosis or dementia or mental retardation disorder in the patient Severe liver disease High risk of postoperative cardiac complications such as bleeding Patients participating in other trials History of bipolar disorder Patients who have been treated with escitalopram or an antidepressant during the previous month Recent abuse of alcohol and substances Pregnancy and lactation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **41**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization using a computer randomization method, in this method we randomly place each client in the intervention or control group. Randomization unit: individual, Randomization tool and randomization sequence: determined by excel software and RAND Function. allocation concealment:

The type of treatment allocated in the two groups is completely unpredictable. Assignment to groups is also hidden from the researcher and patients by coding the drug and placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This clinical trial is blinded so that the participants, the clinician, , principle researcher,data collector and outcome evaluator do not have any info about the assignment of individuals to the groups. The evaluation of the subjects is done by the external evaluator who is not involved in the research team. The main drug and placebo that are similar (in terms of odour, color, shape and taste) are placed in similar cans having the same weight by a person who is not a member of the research team. Drugs are coded based on random sequence in two groups (A) and (B) and they are numbred randomly. A unique code is assigned to each patient .The researcher provides the drug to the participant according to the coding.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethis committee of University of Social Welfare & Rehabilitation sciences

Street address

University of Social Welfare & Rehabilitation Sciences, Koodakyar street, Velenjac

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2020-09-18, 1399/06/28

Ethics committee reference number

IR.USWR.REC.1399.159

Health conditions studied**1****Description of health condition studied**

Depression Disorder

ICD-10 code

F32.8

ICD-10 code description

Other depressive episodes

Primary outcomes

1

Description

degree of Depression

Timepoint

Beginning of the study (before the intervention): Week 4:
Week 8 (after treatment):

Method of measurement

Beck Depression Inventory (BDI-II)

2

Description

quality of life

Timepoint

Beginning of the study (before the intervention): Week 4
: Week 8 (after treatment):

Method of measurement

Quality of Life questionnaire , 36-Item Short Form (SF-36)

Secondary outcomes

1

Description

Drug complication

Timepoint

2 and 4 weeks after taking the drug

Method of measurement

Checklist of drug side effects

Intervention groups

1

Description

Intervention group: take escitalopram 10 mg: once daily :
oral : prduct by Abidi company :For 8 weeks

Category

Treatment - Drugs

2

Description

Control group: take placebo tablet : Produced by Abaidi
Company: once daily : Oral : For 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Dr.Fatemeh Asadian Kuhistani

Street address

Tehran Heart Research Center., Tehran Heart Center
Hospital., North Kargar Street., Jalal Al-Ahmad
Highway

City

Tehran

Province

Tehran

Postal code

1321465780

Phone

+98 21 8802 9256

Fax

+98 21 8802 9731

Email

F.asadian1392@gmail.com

Web page address

<http://thc.tums.ac.ir/v-1022/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Mohammad Reza khodaie Ardakani

Street address

Vice Chancellor for Research., University of Social
Welfare & Rehabilitation Sciences., Koodakyar st.,
Velenjac

City

Tehran

Province

Tehran

Postal code

1324159876

Phone

+98 21 2218 0093

Email

kh.ardakani@uswr.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Fatemeh Asadian Kuhestani

Position
Psychiatry Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Razi psychiatric Hospital , shahre Rey, Tehran

City
Tehran

Province
Tehran

Postal code
1313913139

Phone
+98 21 3340 1604

Email
f.asadian1392@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Dr. Mohammad Reza khodaie Ardakani

Position
psychiatrist-Associated professor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

Street address
Razi psychiatric Hospital , Shahre Rey, Tehran

City
Tehran

Province
Tehran

Postal code
1313913139

Phone
+98 21 3340 1604

Email

kh.ardakani@uswr.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
Fatemeh Asadian Kuhestani

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Psychiatrics

Street address
Razi psychiatric Hospital , Shahre Rey, Tehran

City
Tehran

Province
Tehran

Postal code
1313913139

Phone
+98 21 3340 1604

Email
f.asadian1392@gmail.com

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

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