

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Aspirin as an augmenting to Sertraline for treating major depressive disorder, a randomized double blind placebo controlled clinical trial

Protocol summary

Summary

(1) Objectives: This study aimed to evaluate the effectiveness of investigating the efficacy of Aspirin as for treating patients with major depressive disorder. (2) Design: General plan of this study is consisted of experimental pre-test and post-test (3) Setting and conduct: 100 patient with major depressive disorder who are able to complete the program will be selected by convenient sampling and will be randomly assigned in two groups: One group receives Sertraline plus aspirin and the other group receives Sertraline plus placebo. (4) Participants including major eligibility criteria: all of patients with major depressive disorder and age between 40 and 80 having coronary artery disease criteria. (5) Interventions: both groups treat with sertraline and treatment group receive aspirin in addition to sertraline. The patients will be assessed at baseline, week 4, and week 8. (6) Main outcome measures: Beck Depression Inventory is used to measure the outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016082829556N1**

Registration date: **2016-10-10, 1395/07/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-10-10, 1395/07/19

Registrant information

Name

Hossein Fahimi

Name of organization / entity

Kashan University of Medical Sciences and Health Services

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2016-09-01, 1395/06/11

Expected recruitment end date

2016-11-01, 1395/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Aspirin as an augmenting to Sertraline for treating major depressive disorder, a randomized double blind placebo controlled clinical trial

Public title

Aspirin as an augmenting to Sertraline for treating major depressive disorder, a randomized double blind placebo controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with major depressive disorder according to DSM-VI, both gender, and aged between 40 and 80 years old, Consent to participate in the study by completing the informed consent form, Having risk factors for coronary heart disease or stroke. Exclusion

criteria: Depression due to physical illness or drug use, A history of gastric ulcers and contraindications for taking aspirin, pregnant women, History of alcohol and substance abuse within 6 months prior to the beginning of the study, positive history of mania, mental retardation, psychosis, using another antidepressant within 4 weeks prior to starting ASA, Candidates for other treatments such as ECT for depression.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

using Table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences and Health Services

Street address

Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Vice chancellor for research of Kashan University of Medical Sciences and Health Services

City

Kashan

Postal code

Approval date

2015-06-01, 1394/03/11

Ethics committee reference number

IR.KAUMS.REC.1394.37

Health conditions studied

1

Description of health condition studied

Major Depressive Disorder

ICD-10 code

F32

ICD-10 code description

Depressive episode

Primary outcomes

1

Description

Depression

Timepoint

baseline, 4 week, and 8 week

Method of measurement

Beck Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Sertraline as a serotonin reuptake inhibitor with 150mg daily dosing for 8 week and is production of Dr Abidi pharmacy. and Aspirin (acetyl salysilic acid) 80mg two times per day for 8 week that is production of Dr Abidi pharmacy.

Category

Treatment - Drugs

2

Description

Sertraline as a serotonin reuptake inhibitor with 150mg daily dosing for 8 week and is production of Dr Abidi pharmacy + placebo for 8 week

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kargarnejad Hospital

Full name of responsible person

dr Fatemeh Ghoreishi

Street address

Kargarnejad Hospital, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Kashan

Full name of responsible person

Dr Qolam Ali Hamidi

Street address

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Pezeshk Blvd, 5th of Qotbe Ravandi Blvd

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Kashan University of Medical Sciences and Health Services, Kashan

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences and Health Services

Full name of responsible person

Hossein Fahimi

Position

Resident of Psychiatry

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary
empty