

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of adding Cinnamon essential oil in the treatment regimen of patients with unipolar non-psychotic major depressive disorder treated with sertraline in postmenopausal women.

Protocol summary

Study aim

Effect of adding Cinnamon essential oil in the treatment regimen of patients with unipolar non-psychotic major depressive disorder treated with sertraline in postmenopausal women.

Design

A clinical trial with parallel groups, double-blind, randomized

Settings and conduct

This study will be a double-blind clinical trial. Forty patients with unilateral major depression of psychotic bread were divided into 2 groups of 20 each. Patients in the first group receive 50 mg of sertraline daily with placebo, the second group receive the same amount of sertraline with 10 drops of cinnamon essential oil daily. Complications and questionnaires are statistically analyzed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with unipolar major depressive disorder diagnosed by a neurologist. Exclusion criteria: patients who have other mental disorders besides unilateral major depression; things like the death of relatives, divorce, marriage, etc. that affect one's mood; Use of other psychiatric drugs.

Intervention groups

We have two intervention groups. the first group of patients is treated with sertraline plus placebo. Group 2: patients treated with sertraline plus 10 drops of cinnamon essential oil daily.

Main outcome variables

Depression score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N21**

Registration date: **2019-10-09, 1398/07/17**

Registration timing: **prospective**

Last update: **2019-10-09, 1398/07/17**

Update count: **0**

Registration date

2019-10-09, 1398/07/17

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-29, 1398/08/07

Expected recruitment end date

2020-04-26, 1399/02/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding Cinnamon essential oil in the treatment regimen of patients with unipolar non-psychotic major

depressive disorder treated with sertraline in postmenopausal women.

Public title

Effect of adding Cinnamon essential oil in the treatment regimen of patients with unipolar non-psychotic major depressive disorder treated with sertraline in postmenopausal women

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with unipolar major depressive disorder diagnosed by a neurologist

Exclusion criteria:

Patients who have other mental disorders besides unilateral major depression. Things like the death of relatives, divorce, marriage, etc. that affect one's mood. Use of other psychiatric drugs.

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The study sample was randomly divided into two groups of 20 people, each by selective envelopes. Thus, each envelope containing one of the two A and B labels represented one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs were placed in envelopes in packages A and B without labeling and without the knowledge of the investigator.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Building No. 2,
University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2018-12-23, 1397/10/02

Ethics committee reference number

IR.SKUMS.REC.1397.218

Health conditions studied

1

Description of health condition studied

Unipolar Major Depression Disorder

ICD-10 code

F32.3

ICD-10 code description

Major depressive disorder, single episode, severe with psychotic features

Primary outcomes

1

Description

Depression score

Timepoint

Before and after treatment

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients are treated with 50 mg sertraline plus placebo. (Placebo is the distilled water given to patients in a glass similar to a cinnamon drop. Due to the fact that the cinnamon drop has no specific taste and taste, the use of distilled water seems appropriate).

Category

Treatment - Drugs

2

Description

Intervention group: patients treated with sertraline 50 mg daily with 10 drops of cinnamon essential oil daily (cinnamon essential oil extract).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Hourivash Ghaderi

Street address

Shariati Blvd., Imam Ali Clinic

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816788640

Phone

+98 38 3224 2696

Email

H.ghaderi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person

Dr. Seyed Kamal Solati (Associate Professor of Psychology)

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

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8815713471

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+98 38 3334 2414

Email

kamal_solati@yahoo.com

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, Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Hourivash Ghaderi

Position

Assistant Professor of Psychiatry

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

No - There is not 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

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

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Imam Ali Clinic

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

After the investigation of researcher request and presentation of required documents will be accessible.

Comments