Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the therapeutic effect of combined Lavandula angustifolia and Dracocephalum ruyschiana extract on sertraline-treated mild to moderate depression patients.

Protocol summary

Study aim

Evaluation of the therapeutic effect of combined Lavandula Angustifolia and Dracocephalum Ruyschiana extract on sertraline-treated mild to moderate depression patients.

Design

a clinical trial with a control group, with parallel groups, single-blind, non-random, phase 0 on 70 patients.

Settings and conduct

Samples were selected from patients referring to Razi Hospital, Tabriz, Iran in 2018. After confirming their depression using approved questionnaires by a specialist, they divided into two groups. The first group received 100 mg sertraline tablets daily, with placebo syrup three times a day (participants were not informed whether they receive the intervention drug or placebo). The second was treated with the herbal syrup containing the extract of Lavender and D.Ruyschiana three times daily, and sertraline tablet (100 mg daily). After two months, they were followed up to re-examine the depressive disorder.

Participants/Inclusion and exclusion criteria

Inclusion criteria were the age of patients between 40 to 65 years, the onset of disease in the last 6 months, and the diagnosis of major depression with mild to moderate level. Exclusion criteria were individuals with neurological and physical disorders, mental disorders other than generalized anxiety disorder, and using medications in one past month.

Intervention groups

Participants were divided into two groups of 35 people. One group, along with daily 100 mg of sertraline, consumed a syrup containing selected extracts for two months, three times a day, one tablespoon at a time. The other group, along with sertraline, took the placebo syrup with the same prescription.

Main outcome variables

Two months after taking the prescribed syrups along with sertraline, patients returned to the doctor and had a "back test" to check for depression.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047216N2**
Registration date: **2020-07-04, 1399/04/14**
Registration timing: **retrospective**

Last update: **2020-07-04, 1399/04/14**
Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Majid Khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-21, 1396/12/02

Expected recruitment end date

2018-07-20, 1397/04/29

Actual recruitment start date

2018-02-21, 1396/12/02

Actual recruitment end date
2018-08-10, 1397/05/19
Trial completion date
2018-08-10, 1397/05/19

Scientific title
Evaluation of the therapeutic effect of combined Lavandula angustifolia and Dracocephalum ruyschiana extract on sertraline-treated mild to moderate depression patients.

Public title
The effect of the combination of Lavandula angustifolia and Dracocephalum ruyschiana on mild to moderate depression
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
the onset of disease in the last 6 months diagnosis of major depression with mild to moderate level.
Exclusion criteria:
neurological and physical disorders, mental disorders other than generalized anxiety disorder using medication in the past month
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **70**
Actual sample size reached: **70**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
En The study was conducted as a single-blind. Given that the appearance and taste of the syrup containing L.Angustifolia and D.Ruyschiana extract are similar to the placebo syrup, patients were not informed about the nature of it and they didn't know whether they were the main drug or Placebo.
Placebo
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
Medical Ethics Committee, third floor, second central building, Medical Sciences University, Golgasht street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date
2018-07-02, 1397/04/11
Ethics committee reference number
IR.TBZMED.REC.1397.300

Health conditions studied

1

Description of health condition studied
Major Depression
ICD-10 code
F32.9
ICD-10 code description
Major depressive disorder, single episode, unspecified

Primary outcomes

1

Description
Depression
Timepoint
Evaluation of the rate of depression with a "back test (BDI)" at the beginning of the study and 60 days after taking the syrup containing the extracts
Method of measurement
The Beck Depression Inventory (BDI) questionnaire was used for evaluation of the effects of the intervention. This scale is one of the most valid diagnostic tools for depression whose validity and reliability have been confirmed in various studies

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Thirty-five people, who have diagnosed with depression by a specialist, received 100 mg of sertraline tablets and syrup containing two units of L. Angustifolia extract and one unit of D. Ruyschiana extract three times a day, one tablespoon at a time.

Category
Treatment - Drugs

2

Description
Control group: Control group: including thirty-five people who their clinical features are the same as the intervention group, took 100 mg of sertraline tablets and placebo syrup three times a day, one tablespoon at a time.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi hospital of Tabriz University of Medical Sciences
Full name of responsible person
Alireza Shafiee
Street address
Shahid Bakeri (Elgoli) Boulevard, Tabriz
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shafieear@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr.Khalili Ansarin
Street address
Tuberculosis and lung diseases research center, Pashmineh street, Golgasht street
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5142954481
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khalili876@gmail.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
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Position
Researcher
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

"There is no further information"

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available