

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of *Nepeta mentoithes* Boiss & Bohse and a common anti depressant drug (Sertraline) in mild to moderate major depression

Protocol summary

Summary

The aim of this study is to assess the efficacy of *Nepeta menthoides* as an antidepressant agent in major depression treatment, in a 6 week randomized double-blind controlled trial. A total of 60 adult outpatients between 18-65 ages referring to psychiatry clinic of Shiraz medical university, who meet Becks depression inventory (BDI-II) and DSM-V-TR criteria for major depression and their diagnosis is confirmed by at least two psychiatrists are randomly allocated into two groups (30 patients in each) and assign to receive 400 mg of dried powdery formation of a traditional decoction from *Nepeta menthoides* or 50 mg of sertraline in the uniformed capsules twice daily (in the morning and 1-2 hours before sleeping time at night). Patients who may have other conditions assuming depression such as hypothyroidism, psychiatric disorders except for major depression, mental disorders such as dementia or mental retardation, allergy to *Nepeta menthoides* or other Mint family (Lamiaceae) plants, substance dependency, pregnancy, suicidal thinking or needing to electroconvulsive therapy or not having informed consent are excluded. Severity of depression and anxiety (by Beck inventory for depression and anxiety) and also common possible side effects of drugs will assess in baseline, 2nd week, 4th week and then two weeks after the end of the intervention (in 6th week)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015031521469N1**
Registration date: **2015-06-03, 1394/03/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-03, 1394/03/13

Registrant information

Name

Sepideh Kolouri

Name of organization / entity

Shiraz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 71 3627 2988

Email address

kolouri@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Shiraz University of Medical Science

Expected recruitment start date

2015-04-07, 1394/01/18

Expected recruitment end date

2015-07-07, 1394/04/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of *Nepeta mentoithes* Boiss & Bohse and a common anti depressant drug (Sertraline) in mild to moderate major depression

Public title

Efficacy of *Nepeta Menthoides* in depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Adult outpatients between 18-65 referring to psychiatry clinic of Shiraz medical university; meet Becks depression inventory (BDI-II) and DSM-V-TR criteria for mild to moderate major depression; confirmation of the diagnosis by at least two psychiatrist; and informed consent. Exclusion criteria: Having other conditions assuming depression such as: hypothyroidism, psychiatric disorders except for mild to moderate major depression, mental disorders i.e. dementia or mental retardation; allergy to Nepeta Menthoides or other mentheae family (Lamiaceaes); substance dependency; pregnancy; suicidal thinking or needing to electroconvulsive therapy; not having informed consent

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: Blocked randomization; Blinding with use of Sertraline in the same capsules for control group, all capsules are similar in size and colour, boxes in which capsules pack have the same shape in both groups. Patients and researcher who evaluate study out comes and even though the data analyzer are blind and do not know which group receives Sertraline or Nepeta .

Secondary Ids

1

Registry name

Iranian Registry of Clinical Trial

Secondary trial Id

CT- 9470 - 7440

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Shiraz University of Medical Science

Street address

Vice chancellor for research and technology office, Shiraz University of Medical Science, Zand street, Shiraz

City

Shiraz

Postal code

71345-1978

Approval date

2015-04-07, 1394/01/18

Ethics committee reference number

CT-9470-7440

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0, F32

ICD-10 code description

Mild depressive episode, moderate depressive episode, recurrent depressive disorder current episode mild, recurrent depressive disorder current episode moderate

2

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Other anxiety disorders

Primary outcomes

1

Description

severity of depression

Timepoint

At the base line, 2nd week, 4th week after beginning of intervention and then in 6th week (2 weeks after the end of intervention)

Method of measurement

Beck depression inventory (BDI-II) score

Secondary outcomes

1

Description

Side effects profile

Timepoint

At the base line, 2nd week, 4th week after beginning of intervention and then in 6th week (2 weeks after the end of intervention)

Method of measurement

Clinical interview and physical examination and list in a table

2

Description

Severity of anxiety

Timepoint

At the base line, 2nd week, 4th week after beginning of intervention and then in 6th week (2 weeks after the end of intervention)

Method of measurement

Beck anxiety inventory (BAI) score

Intervention groups

1

Description

One 400 mg oral capsule from Nepeta menthoides aerial parts freeze-dried water extract (extract concentration, 10%), twice daily (one in morning half hour before breakfast and one at night 1-2 hour before usual sleep time) for one month

Category

Treatment - Drugs

2

Description

Sertraline (Sertrabiol manufactured by Bakhtar Bioshimi Co.) , 50 mg in each capsule, one capsule twice daily

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Psychiatry Clinic

Full name of responsible person

Sepideh koloury

Street address

Hafez Hospital, Chamran Blvd., Shiraz

City

Shiraz

2

Recruitment center

Name of recruitment center

Emamreza clinic

Full name of responsible person

Sepideh koloury

Street address

Namazi Sq., Zand St., Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Science

Full name of responsible person

Dr.Seyed Basir Hashemi

Street address

Vice chancellor for research and technology, Shiraz University of Medical Science

City

Shiraz

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, Shiraz University of Medical Science

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

Shiraz University of Medical Science

Full name of responsible person

Sepideh Koloury

Position

MD, PhD candidate in Traditional Medicine

Other areas of specialty/work

Street address

Traditional Persian Medicine college, School of Medicine, Imam Hossein Sq., Zand St., Shiraz

City

Shiraz

Postal code

7194647989

Phone

+98 71 3233 7589

Fax

+98 71 3233 8476

Email

kolouri@sums.ac.ir, sepidehkolouri@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Ali Firoozabadi

Position

Psychiatrist, Associated professor

Other areas of specialty/work**Street address**

Shiraz Department of psychiatry, Hafez hospital,
Chamran Blvd., Shiraz

City

Shiraz

Postal code

71946-34786

Phone

+98 71 3627 9319

Fax

+98 71 3627 9319

Email

firooza@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

Sepideh kolouri

Position

MD.PhD candidate in Traditional Medicine

Other areas of specialty/work**Street address**

Traditional Persian Medicine college, School of
Medicine, Imam Hossein Sq., Zand St., Shiraz

City

Shiraz

Postal code

7194647989

Phone

+98 71 3627 2988

Fax

+98 71 3233 8476

Email

kolouri@sums.ac.ir, sepidehkolouri@yahoo.com

Web page address

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