

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison between treatment with Bosweilia Serrata versus placebo in improving Mild cognitive dementia (MCI)

Protocol summary

Summary

Mild cognitive impairment are the first stage of dementia. Due to the progression of irreversible dementia, the best time to do any preventative action is the MCI stage. Currently, an effective treatment has not been confirmed at this stage. BosweiliaSerrata, so far,had been used for enhancing memory and learning skills among Iranian and Muslims . The present study aimed to investigate the effect of Bosweilia Serrata on the improvement of mild mental impairment (MCI) . In a randomized double-blind clinical trial, in Kerman in southeastern Iran 80 patients were enrolled in the intervention group and the placebo group. At baseline, after evaluation by Moca test, they were received intervention and were followed-up for 3 months and then were evaluated again . finally groups were compared by statistic tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402088430N8**

Registration date: **2015-03-12, 1393/12/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-12, 1393/12/21

Registrant information

Name

Farhad Iranmanesh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1226 2629

Email address

fpp_farhad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Kerman University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between treatment with Bosweilia Serrata versus placebo in improving Mild cognitive dementia (MCI)

Public title

Effect of Bosweilia Serrata in treatment of Mild cognitive dementia (MCI)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Confirmation of MCI related to Peterson criterion; Lack of contraindication for taking Bosweili ; Points less than 7 in BECK test ; Normal brain MRI

Exclusion criteria:Not MCI related to Peterson criterion; contraindication to taking Bosweili ; Points more than 7 in BECK test ;Abnormal brain MRI

Age

From **55 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University

Street address

Shafa Intersection ,Islamic Republic of Blvd,Kerman

City

kerman

Postal code

7619813159

Approval date

2013-08-23, 1392/06/01

Ethics committee reference number

315/92/5

Health conditions studied

1

Description of health condition studied

Dementia NOS

ICD-10 code

F03

ICD-10 code description

unclassified dementia

Primary outcomes

1

Description

MCI (mild mental impairment)

Timepoint

Baseline & 3months after the intervention

Method of measurement

MOCA test

Secondary outcomes

1

Description

Evaluation of improving MCI

Timepoint

After 3 months intervention

Method of measurement

MOCA test

Intervention groups

1

Description

"Intervention group" : capsule Bosweilia, 300mg, BID , 3 months

Category

Treatment - Drugs

2

Description

"Control group" : capsule placebo, BID ,3months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Training & Sciences Center

Full name of responsible person

Doctor behnaz sedighii

Street address

Shafa Street ,Islamic Republic of BLV,Kerman

City

kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of kerman University of Medical Sciences

Full name of responsible person

Hosseinali Ebrahimi

Street address

Center for Neuroscience Research ,Shafa Hospital ,Shafa Street,Kerman

City

Kerman

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 kerman University of Medical Sciences

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
empty

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences and Health Services

Full name of responsible person
Kave Shafii

Position
Assistant professor

Other areas of specialty/work

Street address
Islamic Republic of BLV.kerman

City
kerman

Postal code
7618751151

Phone
+98 34 3211 5780

Fax
+98 34 3211 5817

Email
shafahospital@kmu.ac.ir

Web page address
[htt://shafah.kmu.ac.ir](http://shafah.kmu.ac.ir)

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences and Health Services

Full name of responsible person
Soheila Rezakhani

Position
Neurology Assistant

Other areas of specialty/work

Street address
Shafa Hospital,Kerman

City
kerman

Postal code
7618751151

Phone
+98 34 3211 5780

Fax
+98 34 3211 5817

Email
drrezakhani@gmail.com ; shafa hospital@kmu.ac.ir

Web page address
[htt://shafah.kmu.ac.ir](http://shafah.kmu.ac.ir)

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences and Health Services

Full name of responsible person
Soheila Rezakhani

Position
Neurology Assistant

Other areas of specialty/work

Street address
Shafa HospitalL ,Kerman

City
Kerman

Postal code
7618751151

Phone
+98 34 3211 5780

Fax
+98 34 3211 5817

Email
drrezakhani@gmail.com ; shafa hospital@kmu.ac.ir

Web page address
[htt://shafah.kmu.ac.ir](http://shafah.kmu.ac.ir)

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