Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Assessment of the impact of a memory enhancer traditional oral formulation in management of dementia, a randomized controlled clinical trial.

Protocol summary

Study aim
provide a memory enhancement supplement using traditional medicine

Design
To be included in the study, first the diagnosis of Alzheimer's disease is made based on a questionnaire and initial paraclinical examinations include brain imaging and metabolic evaluation and determination of serum TSH and vitamin B12 levels.

Settings and conduct
The intervention group consumes 4 capsules of herbal medicines containing piper and black cumin (2 in the morning and 2 at night) beside a conventional anti alzheimer disease drug for 6 months.

Participants/Inclusion and exclusion criteria
no pregnancy or breast feeding no cardiovascular disease no presents of depression no sensitivity to herbal medicines presents in formulation

Intervention groups
The intervention group consumes 4 capsules of herbal medicines containing piper and black cumin (2 in the morning and 2 at night) beside a conventional anti alzheimer disease drug for 6 months.

Main outcome variables
serum B12؛ serum TSH

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191212045709N3**
Registration date: **2020-11-14, 1399/08/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-14, 1399/08/24**
Update count: **0**

Registration date
2020-11-14, 1399/08/24

Registrant information
Name
Ramin Ansari
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the impact of a memory enhancer traditional oral formulation in management of dementia, a randomized controlled clinical trial.

Public title
Assessment of the impact of a memory enhancer traditional oral formulation in management of dementia, a randomized controlled clinical trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

diagnosis of dementia based on DSM criteria

Exclusion criteria:

patients with cardiovascular disease pregnancy breast feeding sensitivity to herbal medicines present in formulation patients with depression patients with peptic ulcer disease

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 66 patients were randomly divided in to two groups of 33 each in a randomized double-blind placebo-controlled design using permuted block randomization method. Samples are randomized by random blocking method with 4 blocks and by using the table of random numbers of the Random Allocation Software. Blocking and allocation sequencing for concealment will be done by the person not involved in the research. Minimum sample size for each group was 13 patients. All patients received 2 capsules of the same-looking drug or placebo twice daily for 6 months.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be a double blind trial and only the evaluator knows the results and the code of the drug or placebo group.The capsules of the drug group and the placebo are quite similar in appearance.The drug and placebo groups will be separated by receiving a code.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

shiraz- zand street

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7139745197

Approval date

2019-10-26, 1398/08/04

Ethics committee reference number

IR.SUMS.REC.1398.963

Health conditions studied

1

Description of health condition studied

alzheimer disease

ICD-10 code

G32

ICD-10 code description

Other degenerative disorders of nervous system in diseases classified elsewhere

Primary outcomes

1

Description

TSH serum level

Timepoint

every 6 months

Method of measurement

serum sample

2

Description

B12 serum level

Timepoint

every 6 months

Method of measurement

serum sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: take 4 capsules daily, including pepper (one part), black cumin (one part) and sugar (3 parts) along with underlying drugs to control Alzheimer's for 6 months. The total consumption of the product per day is equal to 4.2 grams.

Category

Treatment - Drugs

2

Description
Control group: take 4 capsules containing starch daily as a placebo along with underlying drugs to control Alzheimer's for 6 months. Brain imaging and measurement of B12 and TSH levels are performed at the beginning and end of the study.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Mehdi Zarshenas
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Person responsible for updating data

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

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