Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of nanocurcumin on brain volumetery and cognitive function of patients with Alzheimer’s disease-Interventional - Randomized controlled clinical trial

Protocol summary

Study aim
Investigating the effect of nanocurcumin on brain volumetery and cognitive function in patients with Alzheimer’s disease

Design
A randomized, double blinded ,and controlled clinical trial with 30 patients with Alzheimer’s disease who will be classified in a group receiving nanocurcumin and a group receiving placebo and followed for 6 months during 2026.

Settings and conduct
Patients with Alzheimer’s disease who diagnosed by a neurologist in Shiraz Emam Reza center or office enrolled based on inclusion criteria by a team member; then they receive nanocurcumin or placebo with double blind approach (patients and researchers) and will undergo brain MRI in Namazi hospital and perform cognitive test(MOCA) at the beginning of study and after 6 months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients who diagnosed as mild or moderate Alzheimer’s disease based on DSM-5 and NIA-AA. 50-85 years old patients. Ability to do cognitive tests and MRI. Exclusion criteria: Patients with other neurological conditions like Parkinson’s disease and stroke. Use of anti inflammatory and antioxidants medications during study. Any contraindications for MRI

Intervention groups
Some patients will take nanocurcumin and other patients will receive placebo

Main outcome variables
Brain volume alterations(volumetery based on MRI)cognitive function alterations(MoCA test)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20231016059737N3**
Registration date: **2026-04-27, 1405/02/07**
Registration timing: **prospective**

Last update: **2026-04-27, 1405/02/07**
Update count: **0**

Registration date
2026-04-27, 1405/02/07

Registrant information

Name
Vahid Reza Ostovan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3612 1065

Email address
ostovanv@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of nanocurcumin on brain volumetery and cognitive function of patients with

Alzheimer’s disease-Interventional - Randomized controlled clinical trial

Public title
Investigating the effect of nanocurcumin on patients with Alzheimer’s disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients diagnosed with mild or moderate Alzheimer’s disease based on DSM-5 and NIA-AA 50-85 years old patients Ability to do cognitive tests and MRI
Exclusion criteria:
Patients with other neurological diseases such as Parkinson’s disease, stroke Use of anti-inflammatory or antioxidant medications Any contraindications for MRI
Age
From **50 years** old to **85 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are allocated with block randomization approach in quadruple blocks and considering two stratification factors including gender and severity of disease (mild and moderate). Medications are provided in similar codes and packaging to patients and researchers be unaware about the type of intervention(allocation concealment). A member of team who doesn’t contribute in randomization and intervention presenting, will select patients based on inclusion criteria.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants, medical team members and researchers are blind about type of intervention (Curcumin vs Placebo). capsules of Curcumin and Placebo are completely similar in shape, color, taste and odor. Also, Data analysts are blind at groups allocation to prevent the biases in results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Faculty of Medicine, Shiraz University of Medical Sciences
Street address
Zand street
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2026-01-29, 1404/11/09
Ethics committee reference number
IR.SUMS.MED.REC.1404.588

Health conditions studied

1

Description of health condition studied
Alzheimer’s disease
ICD-10 code
G30.9
ICD-10 code description
Alzheimer's disease, unspecified

Primary outcomes

1

Description
Brain volume
Timepoint
Beginning of the study and after 6 months of intervention
Method of measurement
1.5Tesla structural MRI

2

Description
Cognitive function
Timepoint
At the beginning of study and after 6 months of intervention
Method of measurement
Montreal Cognitive Assessment (MoCA) test

Secondary outcomes

1

Description
Demographic factor(age)
Timepoint

At the beginning of study

Method of measurement

Based on date of birth

2

Description

Gender

Timepoint

At the beginning of study

Method of measurement

Inquiring about gender

Intervention groups

1

Description

Intervention group: patients with Alzheimer's disease who will receive nanocurcumin soft gel (exirnanosina pharmaceutical company)at a dose of 40 mg per day for six months.

Category

Treatment - Drugs

2

Description

Control group: patients with Alzheimer's disease who will receive one soft gel of placebo per (similar to nanucorcumin in shape, size and color) per day for six months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Imam Reza clinic

Full name of responsible person

Vahidreza OStovan

Street address

Imam Reza special and subspeciality, next to Namazi hospital, Namazi Square , Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134814734

Phone

+98 71 3647 4313

Email

ostovanv@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Hamid Mohammadi

Street address

Research and Technology Deputy,7th Floor, Shiraz University of Medical Sciences Central Building, Zand Street

City

Shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

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

Vahidreza ostovan

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Neurology Department Office, Shahid Motazedi Educational and Medical Center, Namazi Square, Shiraz,Iran

City

Shiraz

Province

Fars

Postal code

71348714737

Phone
+98 71 3612 1000
Email
ostovanv@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vahidreza Ostovan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Shahid Motari Educational and Medical Center, Namazi sq, Zand st.
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3612 1065
Email
Ostovanv@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Vahidreza Ostovan
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Shahid Motahari Center, Namazi sq, Zand street
City
Shiraz
Province
Fars
Postal code
71348714737
Phone
+98 71 3612 1065
Email
ostovanv@gmail.com

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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable