Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Cyperus rotundus herbal oral product on the treatment of mild to moderate Alzheimer disease.

Protocol summary

Study aim
investigating the efficacy of Cyperus rotundus herbal oral product on the treatment of mild to moderate Alzheimer disease.

Design
A clinical trial with a control group, with a parallel group, double-blind, randomized, phase 2-1 on 30 patients, for randomization, the rad function of Excel software was used.

Settings and conduct
Patients with mild to moderate Alzheimer's who are referred to a neurologist's office or the Alzheimer's Clinic of Iran are randomly assigned to the study groups (random allocation rule). The researcher and the patient do not know about the allocation of the drug or placebo until the end of the study, and the study is a two-way blind.

Participants/Inclusion and exclusion criteria
Inclusion: age over 55 years MMSE score between 16 and 22, Or level 4 or 5 on the FAST test Exclusion: Severe depression, Having uncontrolled metabolic diseases Substance abuse and alcohol dependence

Intervention groups
The intervention group received capsules containing 250 mg of dried cyperus rotundus root powder prepared by Sanabel Pharma co.Ltd twice a day for 8 weeks and the placebo group received capsules containing breadcrumbs with the same taste, shape and aroma produced by Sanabel Pharma co.Ltd twice a day for 8 weeks.

Main outcome variables
Brain Mizaj Mental status Cognitive function Alzheimer's severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220625055269N1**
Registration date: **2023-02-26, 1401/12/07**
Registration timing: **prospective**

Last update: **2023-02-26, 1401/12/07**
Update count: **0**

Registration date
2023-02-26, 1401/12/07

Registrant information

Name
Leila Moein Lashkajani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2288 2596

Email address
leilamoein@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-06, 1401/12/15

Expected recruitment end date
2023-06-22, 1402/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Cyperus rotundus herbal oral product on the treatment of mild to moderate Alzheimer disease.

Public title
the effect of Cyperus rotundus herbal oral product on the

treatment of mild to moderate Alzheimer disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female over the age of fifty-five with mild to moderate Alzheimer's disease diagnosed by a neurologist according to the NINCDS-ADRDA criteria.

Exclusion criteria:

major depression Having a congenital cognitive disorder Structural disorders of the brain poor control diabetes

Age

From **55 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

computer generated list of random numbers (random number generator) random is generated by the statistician by a computer software. The pharmacist numbers the drug containers based on the allocation sequence. The PI enrolls the participants and assigns them to interventions.

Blinding (investigator's opinion)

Double blinded

Blinding description

Drugs and placebos are prepared by a person other than the researcher and colleagues involved in the research in identical containers with the same label, shape and aroma, and the researcher and the patient have no knowledge of the presence of a placebo or real medicine in the medicine package.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical ethic committee of Shahed university

Street address

Zarafshan ave, Simaye Iran Ave

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2023-01-02, 1401/10/12

Ethics committee reference number

IR.SHAHED.REC.1401.118

Health conditions studied

1

Description of health condition studied

Alzheimer

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Cognitive function

Timepoint

week 0, week 4 and week 8

Method of measurement

MMSE & FAST questionnaire

2

Description

Brain Mezaj

Timepoint

week 0 and 8

Method of measurement

Fattahi bran Mezaj questioner

Secondary outcomes

1

Description

Alzheimer severity

Timepoint

week 0 and 8

Method of measurement

clinical dementia rating scale-CDR

Intervention groups

1

Description

The intervention group received capsules containing 250 mg of dried Saad Kofi root powder prepared by Sanabel Pharma Co.Ltd twice a day for 8 weeks. MMSE, FAST,

CDR cognitive tests are taken from patients before the study and at the end of the eighth week by standard questionnaires. Before the start of the study and at the end of the fourth and eighth weeks, the patients are visited by a neurologist for free, and whenever necessary, the patients can contact the doctor in charge of the study by phone and ask him from Inform the possible side effects of the drug.

Category

Treatment - Drugs

2

Description

Control group: The control group also received oral capsules containing breadcrumbs made by Sanabel Pharma Co.Ltd twice a day for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of Neurologists and Iran Alzheimer's Association Clinic

Full name of responsible person

Leila Moein Lashkajani

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3rd Dashtestan, Pasdaran ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Leila Moein Lashkajani

Street address

The beginning of the Tehran-Qom freeway, in front of the shrine of Imam Khomeini

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Email

leilamoein@gmail.com

Web page address

https://shahed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University

Proportion provided by this source

20

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

Shahed University

Full name of responsible person

Leila Moein Lashkajani

Position

physician, PHD student of Persian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
In order to comply with the principle of confidentiality and non-disclosure of patients' private and confidential information
Study Protocol
No - There is not 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