

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Clinical trial of the effect of Silymarin on blood and imaging biomarkers of Alzheimer's patients with dyslipidemia

Protocol summary

Study aim

Determination of the effect of Silymarin on imaging and blood biomarkers of Alzheimer's patients with dyslipidemia

Design

This is a double-blind phase 3 clinical trial and using block randomization method, 36 patient with Alzheimer's disease are divided into 3 equal groups. Rand function of Excel software is used for randomization.

Settings and conduct

Neuropsychological evaluations are performed for 36 AD patients who have referred to Ziaeian and Roozbeh hospitals at Tehran city. MRS imaging and biomarkers are performed at Saadatabad Imaging Center in Tehran. Blood biomarkers and biochemical parameters are analyzed in the comprehensive laboratory of Iran University of Medical Sciences. Six months later, all assessments and tests will be performed again. Blinding of patients is facilitated by the use of similar medicine and placebo. Neurologist, other researchers and data analyzer are also blind.

Participants/Inclusion and exclusion criteria

Inclusion-criteria: 1- 60-80 years, 2-with sporadic mild-degree Alzheimer's disease, 3-No history of brain-surgery and chronic-renal failure. Exclusion criteria: 1-Smoking and drug abuse during the study, 2-Lack or irregular use of medications.

Intervention groups

Patients will be divided into the following 3-groups: 1- First intervention group: Patients receive routine medications and three 140 mg Silymarin tablets daily for 6-months. 2-Control group: Patients receive routine medications and placebo (three-times a day) for 6 months. 3-Second intervention group: Patients receive routine medications and three Rosuvastatin tablets a day for 6 months.

Main outcome variables

Determination of concentration of the brain metabolites, mental and cognitive status and serum level of

antioxidant and diagnostic markers in Alzheimer's patients, before and 6 months after intervention in relevant groups

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210901052360N1**

Registration date: **2021-10-26, 1400/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-26, 1400/08/04**

Update count: **0**

Registration date

2021-10-26, 1400/08/04

Registrant information

Name

Auob Rustamzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4567

Email address

rostamzadeh.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-25, 1400/08/03

Expected recruitment end date

2022-06-10, 1401/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of Silymarin on blood and imaging biomarkers of Alzheimer's patients with dyslipidemia

Public title
The effect of Silymarin on dyslipidemic patients with Alzheimer's disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patient has sporadic Alzheimer's disease. The patient has a mild degree of Alzheimer's disease. The patient has dyslipidemia. Patients whose Alzheimer's disease has been confirmed by clinical evaluation or imaging techniques and biochemical tests by a neurologist.
Exclusion criteria:
The patient has no history of viral hepatitis. The patient has not had alcohol misuse, smoking or drug abuse in the last month. The patient should not take chemotherapy drugs. The patient does not have active rheumatic disorders. The patient does not have diabetes and uncontrolled hypertension. The patient has no history of brain surgery. The patient does not have advanced heart failure, acute cardiovascular disease, or chronic renal failure. The patient does not have hypothyroidism.

Age
From **60 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization in this study is done through block randomization with size of 6. The randomization unit is of individual type. The randomization tool of this study is Excel software and this software is also used to create random sequences. For allocation concealment, a clinical trial specialist who is not a project collaborator in a separate center, after registering the participants' information, defines the separate code on medicine box for each patient and informs the research team about the code.

Blinding (investigator's opinion)

Double blinded

Blinding description
Blinding of patients is facilitated by the use of similar medicine and placebo. Neurologist and other researchers only have access to the serial number of the medicine box. The data analyzer has access to grouping but is still blind to the actual medicine and placebo information.

Placebo
Used

Assignment
Parallel

Other design features
Patients' diets do not change when they enter the study, and their routine medication administration do not stop

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-10-16, 1400/07/24

Ethics committee reference number

IR.IUMS.FMD.REC.1400.409

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30.1

ICD-10 code description

Alzheimer's disease with late onset

Primary outcomes

1

Description

N-acetyl-aspartate (NAA) metabolite

Timepoint

Before and after the intervention (6 months)

Method of measurement

Part per million (ppm) in MR spectroscopy and

percentage

2

Description

Amyloid beta-42 (A β 42)

Timepoint

Before and after the intervention (6 months)

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Low Density Lipoprotein Receptor-Related Protein-1 (LRP1)

Timepoint

Before and after the intervention (6 months)

Method of measurement

ELISA kit

2

Description

Lactate (Lac) metabolite

Timepoint

Before and after the intervention (6 months)

Method of measurement

Part per million (ppm) in MR spectroscopy and percentage

3

Description

Choline (Cho) metabolite

Timepoint

Before and after the intervention (6 months)

Method of measurement

Part per million (ppm) in MR spectroscopy and percentage

4

Description

Myoinositol (ml) metabolite

Timepoint

Before and after the intervention (6 months)

Method of measurement

Part per million (ppm) in MR spectroscopy and percentage

5

Description

Creatine (Cr) metabolite

Timepoint

Before and after the intervention (6 months)

Method of measurement

Part per million (ppm) in MR spectroscopy and percentage

6

Description

Correlation between imaging and blood biomarkers with clinical findings

Timepoint

Before and after the intervention (6 months)

Method of measurement

Percent with Pearson statistical test

7

Description

Mini-Mental State Exam (MMSE)

Timepoint

Before and after the intervention (6 months)

Method of measurement

MMSE questionnaire

8

Description

Clinical dementia rating (CDR)

Timepoint

Before and after the intervention (6 months)

Method of measurement

CDR questionnaire

9

Description

High density lipoprotein (HDL)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

10

Description

Low density lipoprotein (LDL)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

11

Description

Triglycerides (TG)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

12

Description

Catalase (CAT)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

13

Description

Superoxide dismutase (SOD)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

14

Description

Malondialdehyde (MDA)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

15

Description

Alanine aminotransferase (ALT)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

16

Description

Aspartate aminotransferase (AST)

Timepoint

Before and after the intervention (6 months)

Method of measurement

Spectrophotometry

Intervention groups

1

Description

First intervention group: In addition to taking routine medications (10 mg Donepezil/6 mg Rivastigmine) once daily, patients receive 140 mg Silymarin tablets (Livergol 140 mg; Goldaru Pharmaceutical Company; Isfahan, Iran) orally three times daily with an interval of eight hours for 6 months.

Category

Treatment - Drugs

2

Description

Control group: In addition to taking routine medications (10 mg Donepezil/6 mg Rivastigmine) once daily, patients receive 140 mg placebo tablets (Livergol 140 mg; Goldaru Pharmaceutical Company; Isfahan, Iran) orally three times daily with an interval of eight hours for 6 months.

Category

Placebo

3

Description

Second intervention group: In addition to taking routine medications (10 mg Donepezil/6 mg Rivastigmine) once daily, patients receive 10 mg Rosuvastatin tablets (Ropixon 10 mg; Abidi Pharmaceutical Company; Tehran, Iran) orally three times daily with an interval of eight hours for 6 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ziaeian Hospital

Full name of responsible person

Fatemeh Moradi

Street address

Qazvin St., Abuzar Square, 20 meters from Abuzar, Ziaeian Medical Center

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2

Recruitment center**Name of recruitment center**

Roozbeh Psychiatry Hospital

Full name of responsible person

Fatemeh Moradi

Street address

South Kargar Street, below Lashkar Crossroads, Roozbeh Psychiatric Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Auob Rustamzadeh

Position

Ph.D. student in Anatomical Sciences

Latest degree

Master

Other areas of specialty/work

Anatomy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Fatemeh Moradi

Position

Associate Professor of Anatomical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Ph.D. Student in Anatomical Sciences

Latest degree

Master

Other areas of specialty/work

Anatomy

Street address

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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

There is no more 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