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)

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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 (Aβ42)
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 (mI) 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
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Qazvin St., Abuzar Square, 20 meters from Abuzar, Ziaeian Medical Center
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2

Recruitment center
Name of recruitment center
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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
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

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Person responsible for updating data

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Latest degree
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auob2020rustamzade@gmail.com

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