Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Clinical trial of the effect of spirulina supplementation compared with the placebo on insulin resistance, inflammatory factors, biomarkers of oxidative stress and cognitive function in patients with Alzheimer's disease

Protocol summary

Study aim
The aim of this study is to determine the effects of spirulina supplementation on insulin resistance, inflammatory factors, biomarkers of oxidative stress and cognitive function in patients with Alzheimer's disease.

Design
Parallel double-blind (both patients and researchers) randomized controlled clinical trial. Random assignment will be done by the use of computer-generated random numbers.

Settings and conduct
Madar and Shayestegan Welfare Organizations (Shahrekord, Iran).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with Alzheimer's disease and aged 55 to 100 years will be included in this study.
Exclusion criteria: Patients with metabolic syndrome, diabetes, cardiovascular disease, chronic infections, consuming spirulina supplements within 8 weeks prior to the study and taking antioxidants supplements will be excluded.

Intervention groups
Patients will be assigned to receive spirulina supplements (n=30) and placebo (n=30).

Main outcome variables
Insulin resistance, inflammatory factors and biomarkers of oxidative stress, and cognitive function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170612034497N6**
Registration date: **2019-12-04, 1398/09/13**
Registration timing: **registered_while_recruiting**
Last update: **2019-12-04, 1398/09/13**
Update count: **0**

Registration date
2019-12-04, 1398/09/13

Registrant information

Name
Omid Reza Tamtaji

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-30, 1398/05/08

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of the effect of spirulina supplementation compared with the placebo on insulin resistance, inflammatory factors, biomarkers of oxidative stress and cognitive function in patients with Alzheimer's disease

Public title

Effect of spirulina supplementation in treatment of patients with Alzheimer's disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Alzheimer's disease Individuals aged 55 to 90 years

Exclusion criteria:

Patients with metabolic syndrome Patients with cardiovascular disease Patients with chronic infections Consuming spirulina supplements within 8 weeks prior to the study Taking antioxidants supplements Patients with diabetes

Age

From **55 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline, participants based on balanced blocked randomization will be allocated into two groups to take either spirulina supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

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Kashan

Province

Isfehan

Postal code

8715988141

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.Kaums.MEDNT.REC.1398.050

Health conditions studied

1

Description of health condition studied

Alzheimer's disease

ICD-10 code

G30

ICD-10 code description

Alzheimer's disease

Primary outcomes

1

Description

Cognitive function

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Mini Mental State Exam (MMSE)

Secondary outcomes

1

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

ELISA kit

3

Description

Triglycerides

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

LDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

6

Description

High-sensitivity C-reactive protein

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

ELISA kit

7

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

8

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

9

Description

Glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

10

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

11

Description

Fasting blood sugar

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

12

Description

Insulin resistance

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation using HOMA formula

Intervention groups

1

Description

Intervention group: 500 mg spirulina oral capsule (Khalije Fars Biotechnology Development Company), twice a day, for 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo oral capsule (Khalije Fars Biotechnology Development Company), twice a day, for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shayestegan Welfare Organization

Full name of responsible person

Zahra Hosseini

Street address
No. 1, 5th Alley, Bahar Ave, Shahriar Ave, Shahrekord

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2

Recruitment center

Name of recruitment center
Madar Welfare Organization

Full name of responsible person
Fariba Jafarian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

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
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Ebrahim Kouchaki

Position
Neurologist

Latest degree
Specialist

Other areas of specialty/work
Neurology

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Person responsible for updating data

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Omid Reza Tamtaji

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Physiologist

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Physiology

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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