

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### The effect of probiotic supplementation on cognitive function and inflammatory markers in patients with early and late phases of Alzheimer's disease

#### Protocol summary

##### Summary

This study was designed to assess how the early and late phases the disease is sensitive to the probiotic supplementation. In addition to the MMSE cognitive test, measurement of inflammatory factors including IL-6, IL-10, TNF- $\alpha$  and some metabolic parameters are under focus of the present work. The participants are randomly selected (as multi center) from the welfare centers located in Tehran, Kashan and Aran - Bidgol. The sample size is adjust according to sample size formula and previous study; accordingly 60 patients are divided in two control (receiving maltodextrin) and test (receiving probiotic) groups with 30 people in each group. The major criterion for entering the study is Alzheimer associated memory disorder diagnosed by a neurologist through the Mini-Mental State Examination (MMSE) test. The experimenters are blind to the control and test groups during the supplement administration, behavioral test and measuring the inflammatory factors. Hence the investigation will be performed as double blind study. The interventions are administering either maltodextrin (in the control group) or probiotic (in the test group). The primary and secondary variables are the MMSE scores and the serum inflammatory factors, respectively.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017061534549N1**  
Registration date: **2017-10-24, 1396/08/02**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-10-24, 1396/08/02

#### Registrant information

##### Name

Mahmoud Salami

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5562 1157

##### Email address

salami-m@kaums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Kashan University of Medical Sciences - Deputy of Research Zist Takhmir Company

#### Expected recruitment start date

2017-04-21, 1396/02/01

#### Expected recruitment end date

2017-08-23, 1396/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of probiotic supplementation on cognitive function and inflammatory markers in patients with early and late phases of Alzheimer's disease

#### Public title

The effect of probiotic supplementation on cognitive function and inflammatory markers in patients with early and late phases of Alzheimer's disease

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: The patients will be categorized based on the Mini Mental State Examination (MMSE) test, age (65-90) and sex. Exclusion criteria: any disease other than the cognitive problems in the patients such as metabolic disorders

### Age

From **65 years** old to **90 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical committee of Kashan University of Medical Sciences

##### Street address

Physiology Research Center, Kashan University of Medical Sciences

##### City

Kashan

##### Postal code

##### Approval date

2017-05-31, 1396/03/10

##### Ethics committee reference number

IR.kaums.rec.1396.42

## Health conditions studied

### 1

#### Description of health condition studied

Alzheimer,s disease

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Memory (based on Mini Mental State Examination test)

#### Timepoint

before and after 4 months of intervantion

#### Method of measurement

Interview

## Secondary outcomes

### 1

#### Description

Serum inflammatory factors

#### Timepoint

Before and 4 months after intervention

#### Method of measurement

measurments in serum through Elisa kits

## Intervention groups

### 1

#### Description

Intervention group: Probiotics -Including : Bididobacterium lactis,Bifidobacterium bifidum,Bifidobacterium longum And Lactobacillus plantarum,Lactobacillus fermentum, Lactobacillus acidophilus , each person receiving one capsule/day- Each capsule containing 9000000000 bacteria - - duration of treatment: 4 months - product of Zyst Takhmir and Milad Biopharmed Companies

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Maltodextrin -Including orligosacharide with alpha- 1,4 and alpha 1,6 bonds Capsulated maltodextrine - each person receiving one capsule/day - -duration of treatment: 4 months - product of Milad Biopharmed Company

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Golabchi Welfare Organization

##### Full name of responsible person

##### Street address

##### City

Kashan

## 2

### Recruitment center

**Name of recruitment center**

Miaad Welfare Organization

**Full name of responsible person****Street address****City**

Kashan (Ravand)

## 3

### Recruitment center

**Name of recruitment center**

Imam Ali (PBOH) Welfare Organization

**Full name of responsible person****Street address****City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Mahmoud Salami

**Street address**

Physiology Research Center, Kashan University of  
Medical Sciences

**City**

Kashan

**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****Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

### 2

#### Sponsor

**Name of organization / entity**

Zist Takhmir Company

**Full name of responsible person**

Mrs. Tajik

**Street address**

Resalat Square, Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zist Takhmir Company

**Proportion provided by this source****Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Dr. Mahmoud Salami

**Position**

Head of Physiology Research Center-PhD

**Other areas of specialty/work****Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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Dr. Mahmoud Salami

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
**Street address**  
**City**  
**Postal code**  
**Phone**  
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**Fax**  
**Email**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*