# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Investigating the effect of native engineered probiotic supplement on cognitive function and quality of life of Alzheimer's patients

### Protocol summary

**Study aim**
Investigation of the probiotic effects of local strains on cognitive function and quality of life in people with Alzheimer's disease will be done.
**Design**
The study will be a randomized, placebo-controlled trial studying people with mild to moderate AD. Participants will be randomly assigned to receive a probiotic supplement or a placebo for 12 weeks
**Settings and conduct**
People with mild to moderate AD disease in Imam Khomeini Hospital of Urmia
**Participants/Inclusion and exclusion criteria**
Inclusion criteria included subjects with mild to moderate AD, diagnosed by a neurologist or psychiatrist, with a Mini-Mental State Examination (MMSE) score between 10 and 24. Exclusion criteria included subjects with significant hearing or vision impairments, unstable medical conditions, recent hospitalization, recent changes in medication regimen, and recent use of antibiotics or probiotics.
**Intervention groups**
The study will be a randomized, placebo-controlled trial studying people with mild to moderate AD.
**Main outcome variables**
Quality of Life

### General information

**Reason for update**
**Acronym**
LAB
**IRCT registration information**
IRCT registration number: **IRCT20240410061465N2**
Registration date: **2024-04-26, 1403/02/07**
Registration timing: **prospective**

Last update: **2024-04-26, 1403/02/07**
Update count: **0**
**Registration date**
2024-04-26, 1403/02/07

**Registrant information**
**Name**
Hadi Maleki-Kakelar
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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+98 44 3348 6165
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2024-05-21, 1403/03/01
**Expected recruitment end date**
2025-05-22, 1404/03/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of native engineered probiotic supplement on cognitive function and quality of life of Alzheimer's patients

**Public title**
Probiotic supplement for Alzheimer's patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
People with mild to moderate Alzheimer's

**Exclusion criteria:**
Patient non-cooperation during treatment Possible death of the patient during the study according to the nature of the disease

**Age**
From **60 years** old

**Gender**
Both

**Phase**
1

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Research Ethics Committees of Urmia University of Medical Sciences

**Street address**
No 1, Secend alley, Rodaki Avenue, Urmia, Iran.

**City**
Urmia

**Province**
West Azarbaijan

**Postal code**
5719161583

**Approval date**
2024-03-13, 1402/12/23

**Ethics committee reference number**
IR.UMSU.REC.1402.384

## 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**
Quality of Life

**Timepoint**
before the start of the study and after 6 weeks and the end of the study

**Method of measurement**
questionnaire

### 2

**Description**
Cognitive performance of people

**Timepoint**
Start and end of study

**Method of measurement**
questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Patients with mild to moderate Alzheimer's are over 60 years old, diagnosed by a neurologist, with a small mental state examination score between 10 and 24, the dosage is one pill a day, the duration of use is 12 weeks, the pill is in collaboration with zist Company Fermentation is provided.

**Category**
Treatment - Drugs

### 2

**Description**
Control group: Patients with mild to moderate Alzheimer's are over 60 years old and are diagnosed by a neurologist with a score of the Small Mental Status Examination between 10 and 24. The dosage is one placebo per day, the duration of use is 12 weeks, and the pills are in cooperation with Zist Company fermentation is provided.

**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Imam Khomeini Hospital

**Full name of responsible person**
Hadi Maleki-Kakelar

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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Hadi Maleki-Kakelar
**Street address**
No 1, Secend alley, Rodaki Avenue, Urmia, Iran.
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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**
Oroumia 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**
Oroumia University of Medical Sciences
**Full name of responsible person**
Hadi Maleki-Kakelar
**Position**
Assistant Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Medical Biotechnology
**Street address**
3rd Floor, Hakim Jarjani Building, Shafa Street, Ershad Blvd, Cellular and Molecular Research Institute
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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)**
Yes - There is a plan to make this available
**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
**Title and more details about the data/document**
A part of the results related to the main result can be shared.
**When the data will become available and for how long**
6 months after publishing and printing the results
**To whom data/document is available**
It will be available only to researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
It can be used if permission is obtained from the person in charge of the design and giving a reference
**From where data/document is obtainable**
Project manager at Urmia University of Medical Sciences
**What processes are involved for a request to access data/document**
The application to the research and technology vice-chancellor of the university and after review and approval to the project manager requires 2 working weeks.
**Comments**
Does not have