

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Evaluation of the effects of capsules containing probiotics on metabolic parameters, oxidative stress and clinical symptoms of age-related macular degeneration

Protocol summary

Study aim

Determination of the effect of probiotic capsule on metabolic parameters, oxidative stress and clinical signs of age-related macular degeneration (AMD), 1397 in Kashan

Design

This study will be designed as a clinical trial. Double-blind control-placebo is performed on 70 patients with ARMD in the range of 50-85 years old. First, patients are identified based on biochemical findings and a fundoscopic finding with ARMD history. Then they are treated with one of the treatment groups or placebo

Settings and conduct

This clinical trial is performed on 70 individuals with age-related macular degeneration which referred to Kashan Matini Hospital. Individuals based on random Blocks (one per group) will be divided to probiotic or placebo capsule, one per day for 2 months. Individuals checked by the phone monthly and at the beginning and end of the study they will have a visit and blood tests and clinical examinations will be done for them. All drug are presented in the same package and the physician, patients, researcher and statistical analyst are blind. After analyzing data, codes will be decoded.

Participants/Inclusion and exclusion criteria

Entrance criteria: aged 50 to 85 years, diminished vision solely due to AMD Exit criteria: corneal opacity, diabetes, history of retinal vascular disorders, history of retina tear, history of penetrating trauma

Intervention groups

Intervention group: probiotic capsule 500 mg, produced in tak gene company, One number per day for 2 months orally. Control group: placebo capsule 500 Mg, produced in tak gene company, One number per day for 2 months orally.

Main outcome variables

Fasting blood glucose Plasma; Insulin Serum; Insulin

resistance; Hs-CRP; Total glutathione; Macular thickness; Visual acuity

General information

Reason for update

Due to changes occur during the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N30**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **retrospective**

Last update: **2022-12-31, 1401/10/10**

Update count: **1**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1555 0021

Email address

taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-20, 1397/02/30

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

2018-05-20, 1397/02/30
Actual recruitment end date
 2018-11-21, 1397/08/30
Trial completion date
 2019-01-20, 1397/10/30

Scientific title
 Evaluation of the effects of capsules containing probiotics on metabolic parameters, oxidative stress and clinical symptoms of age-related macular degeneration

Public title
 The effect of probiotic capsule on patients with macular degeneration associated with age

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Reduced vision simply because of AMD
Exclusion criteria:
 Corneal opacity Diabetes History of retinal vascular disorders History of retina tear History of penetrating trauma

Age
 From **50 years** old to **85 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **70**
 Actual sample size reached: **70**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Random Blocks (one per group): Patients will be divided into two groups, probiotic (case) and placebo (control). The division of selected subjects will be done randomly in blocks of study using quadrilateral blocks. The division of selected subjects will be done in randomized blocks using six rows of four blocks (ABAB-BABA-ABBA-BAAB-AABB-BBAA). probiotic capsule (A) and placebo group (B). In this way, different scenarios are written on six cards and will be thrown into a bag and 60 cards will be written out of the bag for 15 times, and the order will be written in a sheet.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Drugs and placebo are in the same packaging at the Barij Essence pharmaceutical company . Only the code is written on the packages. Patients and physician do not know the type of drug and after analyzing the data, packet codes are decoded.

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
 Kashan University of Medical Sciences,Qotbe Ravandi Boulevard, Kashan
City
 kashan
Province
 Isfahan
Postal code
 8115187159

Approval date
 2017-12-11, 1396/09/20

Ethics committee reference number
 IR.KAUMS.NUHEPM.REC.1396.16

Health conditions studied

1

Description of health condition studied
 Age-related macular degeneration

ICD-10 code
 H35.3

ICD-10 code description
 Degeneration of macula and posterior pole

Primary outcomes

1

Description
 High sensitive-Critical Reactive Protein

Timepoint
 At the beginning of the study and 2 months after the start of the study

Method of measurement
 ELISA

Secondary outcomes

1

Description
 Visual Acuity

Timepoint
 At the beginning of the study and 2 months after the

start of the study
Method of measurement
Visual Acuity check with Snellen chart

2

Description
Macular thickness

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Central Macular Thickness Evaluate with OCT Instrument

3

Description
Fasting plasma glucose

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Enzymatic Kits

4

Description
Triglycerides

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Enzymatic Kits

5

Description
Low density lipoprotein-cholesterol

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Enzymatic Kits

6

Description
High density lipoprotein-cholesterol

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Enzymatic Kits

7

Description
Total cholesterol

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Enzymatic Kits

8

Description
Very low density lipoprotein-cholesterol

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Standard formula

9

Description
Nitric oxide

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Photospectrometry

10

Description
Malondialdehyde

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Photospectrometry

11

Description
Glutathion

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Photospectrometry

12

Description
Total Anti Oxidant

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
Photospectrometry

13

Description
Insulin

Timepoint
At the beginning of the study and 2 months after the start of the study

Method of measurement
ELISA

14

Description
QUICKI

Timepoint

At the beginning of the study and 2 months after the start of the study

Method of measurement

Standard formula

15**Description**

HOMA-IR

Timepoint

At the beginning of the study and 2 months after the start of the study

Method of measurement

Standard formula

Intervention groups**1****Description**

Intervention group: probiotic capsule 500 MG, produced in tak gene company, One number per day for 2 months orally.

Category

Treatment - Drugs

2**Description**

Control group: placebo capsule 500 MG, produced in Tak gene company, One number per day for 2 months orally.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Matini Hospital

Full name of responsible person

Hasan Farajipoor

Street address

Matini Hospital, Amir Kabir Street, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5534 4271

Email

farajipoor_h@kaums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Hamid Reza Banafshe

Street address

Kashan University of Medical Sciences, Qotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5554 2999

Email

banafsheh_h@kaums.ac.ir

Web page address

http://kaums.ac.ir

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

Hasan Farajipoor

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

Kashan University of Medical Sciences, Qotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Phone

+98 31 5554 0021

Email

farajipoor_h@kaums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

mMohsen Taghizadeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Kashan University of Medical Sciences, Qotbe Ravandi
Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8719675537

Phone

+98 31 5533 3213

Email

taghizadeh_m@kaums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Mohsen Taghizadeh

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Kashan University of Medical Sciences, Qotbe Ravandi
Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

871967537

Phone

+98 31 5533 3213

Email

taghizadeh_m@kaums.ac.ir

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