Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 probotic 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

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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

Isfehan

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 and2 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 capsule500 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Hasan Farajipoor
Position
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Person responsible for updating data

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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