Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of probiotic food supplement on metabolic parameters, oxidative stress and clinical symptoms in patients with diabetic retinopathy

Protocol summary

Study aim

The effect of dietary supplement containing probiotic on metabolic parameters and clinical signs of diabetic retinopathy (DR) in patients referring to Matini Hospital in Kashan, 2018.

Design

Randomized clinical trial, double blind, controlled with placebo, parallel, single center

Settings and conduct

This clinical trial is performed on 72 individuals with diabetic retinopathy which referred to Kashan Matini Hospital.Individuals based on table of random numbers will be divided to probotic or placebo capsule,one per day for 3 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

Inclusion criteria: Age 20 to 70 years; Have each stage of diabetic retinopathy; Normal intraocular pressure Non inclusion criteria: Corneal opacity; Intra-vitreous hemorrhage of the retina; Retinal problems with the exception of diabetic retinopathy; Glaucoma disease or high refractive error; History of any previous retinal treatment; Other diseases of the retina and optic nerve; Ocular hypertension

Intervention groups

Intervention group: probiotic capsule ,One number per day for 3 months orally. Control group: placebo capsule ,One number per day for 3 months orally.

Main outcome variables

Fasting plasma glucose; serum Insulin; Insulin resistance Hs-CRP; Total glutathione; Macular thickness; Visual acuity; Hemoglobin A1C

General information

Reason for update

Due to changes occur during the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20130211012438N29**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **retrospective**

Last update: **2022-08-03, 1401/05/12**
Update count: **1**

Registration date

2019-01-26, 1397/11/06

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
2018-11-21, 1397/08/30

Scientific title
The effect of probiotic food supplement on metabolic parameters, oxidative stress and clinical symptoms in patients with diabetic retinopathy

Public title
the effects of capsules containing probiotics on diabetic retinopathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Have each stage of diabetis retinopathy Normal intraocular pressure
Exclusion criteria:
Corneal opacity Intra-vitreous hemorrhage of the retina, with the exception of diabetic retinopathy Glaucoma disease or high refractive errors History of any previous retinal treatment Other diseases of the retina and optic nerve Ocular hypertension
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **72**
Actual sample size reached: **55**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized based on table of random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
Coding and similar packaging will be used for blinding. Therefore, the physician, patient, researcher and statistical analyzer are blind to the content of the packages. At the end of the study and analysis of data, decoding will be done.
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
2017-12-12, 1396/09/21
Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1396.15

Health conditions studied

1

Description of health condition studied
Diabetic retinopathy
ICD-10 code
H36.0
ICD-10 code description
Diabetic retinopathy

Primary outcomes

1

Description
Visual Acuity
Timepoint
At the beginning of the study and three months after the start of the study
Method of measurement
Visual Acuity check with snellen chart

2

Description
HOMA-IR
Timepoint
At the beginning of the study and three months after the start of the study
Method of measurement
Standard formula

3

Description
Macular thickness
Timepoint
At the beginning of the study and three months after the start of the study

Method of measurement
Central Macular Thickness Evaluate with OCT Instrument

Secondary outcomes

1

Description
Total Anti Oxidant (TAC)
Timepoint
At the beginning and the end of the study
Method of measurement
Photospectrometry

2

Description
Glutathion
Timepoint
At the beginning and the end of the study
Method of measurement
Photospectrometry

3

Description
Malondialdehyde
Timepoint
At the beginning and the end of the study
Method of measurement
Photospectrometry

4

Description
Nitric oxide
Timepoint
At the beginning and the end of the study
Method of measurement
Photospectrometry

5

Description
High sensitive-C reactive protein(hs-CRP)
Timepoint
At the beginning and the end of the study
Method of measurement
ELISA

6

Description
HbA1C
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic Kits

7

Description
Fasting plasma glucose
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic Kits

8

Description
Insulin
Timepoint
At the beginning and the end of the study
Method of measurement
ELISA

9

Description
Triglyceride
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic Kits

10

Description
Total cholesterol
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic Kits

11

Description
Very low density lipoprotein-cholesterol (VLDL-ch)
Timepoint
At the beginning and the end of the study
Method of measurement
Standard formula

12

Description
High density lipoprotein-cholesterol (HDL-ch)
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic Kits

13

Description
Low density lipoprotein-cholesterol (VLDL-ch)
Timepoint
At the beginning and the end of the study
Method of measurement
Enzymatic Kits

14

Description
QUICKI
Timepoint

At the beginning and the end of the study

Method of measurement

Standard formula

Intervention groups

1

Description

Intervention group: probiotic capsule ,One number per day for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: placebo capsule ,One number per day for 12 weeks 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

Isfehan

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

School of Medicine, Qotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

81151-87159

Phone

+98 31 5554 0021

Email

banafsheh_h@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 professor

Latest degree

Subspecialist

Other areas of specialty/work

Ophthalmology

Street address

School of Medicine, Qotbe Ravandi Boulevard, Kashan

City

kashan

Province

Isfehan

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

Mohsen Taghizadeh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address
School of Medicine, Qotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
Postal code
81151-87159
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
MohsenTaghizadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
School of Medicine, Qotbe Ravandi Boulevard, Kashan,Iran
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5554 3198
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