

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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 probiotic 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 diabetic 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**

Isfahan

**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

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

School of Medicine, Qotbe Ravandi Boulevard, Kashan

###### City

Kashan

###### Province

Isfahan

###### 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

Isfahan

###### Postal code

81151-87159

###### Phone

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###### 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

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**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

**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