

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Spirulina Platensis on fasting blood Glucose, Glycosylated Hemoglobin (HbA1c) and Lipid Profile in Type 2 diabetic Patients in Mashhad

Protocol summary

Study aim

Effect of spirulina alga on blood glucose, reducing glycosylated hemoglobin and improving lipid profiles

Design

Clinical trials with a control and intervention group (60 patients in total) will be studied in parallel, one blind and randomized Conditions.

Settings and conduct

60 patients referred to Shahid Ghodsi diabetes Center in Mashhad will be randomly assigned into two intervention and control groups. The control group, which will receive conventional anti-diabetes treatment and placebo, and the treatment group, in addition to its usual treatment, will receive Spirulina powder in two divided doses of 1 g, 12 hours apart. The study lasts for 90 days. Hb A1c is evaluated as an initial outcome immediately before intervention and at the end of the intervention. Lipid profiles (TG, HDL, LDL, Cholesterol) and fasting blood glucose levels are recorded on days 0, 30, 60 and 90. Patients, physicians and data analyst team will be blind on one side.

Participants/Inclusion and exclusion criteria

People entering the study will have type 2 diabetes, ranging in age from 30 to 60 years old, and have been treated with anti-diabetes drugs for less than 5 years. Non-arrival conditions: Not having diabete Having diabete but: Pregnancy and lactation, Patients with phenylketonuria, Patients with autoimmune diseases, Patients with kidney or liver failure Use of antioxidant supplements and vitamins (especially B groups)

Intervention groups

To evaluate the effect of spirulina algae in the both control and treatment groups, HbA1c was evaluated as an initial outcome immediately before the intervention and at the end of the intervention. Also, lipid profiles (TG, HDL, LDL, Cholesterol) and fasting blood glucose levels are recorded on days 0, 30, 60 and 90.

Main outcome variables

Measured variables to assess the effect of intervention: HbA1c, lipid profiles (TG, HDL, LDL, Cholesterol) and FBS levels in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180418039348N1**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Javad Boskabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3657 9723

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-22, 1397/03/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Spirulina Platensis on fasting blood Glucose, Glycosylated Hemoglobin (HbA1c) and Lipid Profile in Type 2 diabetic Patients in Mashhad

Public title
The Effect of Spirulina Platensis on fasting blood Glucose and Lipid Profile in Type 2 diabetic Patients in Mashhad

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Type 2 Diabetes Mellitus Fasting plasma glucose is equal to or greater than 100 to 125 mg / dl The OGTT test equal to or greater than 140 to 199 mg / dl Hb1c: 4.6 to 7.5 Less than 5 years of treatment with anti-diabetes drugs
Exclusion criteria:
 Not having diabetes Pregnancy and lactation Patients with phenylketonuria 36/5000 Patients with autoimmune diseases Patients with kidney or liver failure Use of antioxidant supplements and vitamins (especially B vitamin groups)

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
After completing the consent form, at least 60 patients will be randomly assigned to two groups of control and intervention. The control group, which will receive conventional anti-diabetes treatment and placebo, and the treatment group, in addition to its usual treatment, will receive Spirulina concentrate powder at a dose of 2 g per day (in two divided doses of 1 g, 12 hours apart).

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients participating in the study, the physician and the clinical team evaluating the side effects and efficacy of the drug and the data analyst have been kept blind.

Placebo
Used

Assignment

Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Mashhad University of Medical Sciences
Street address
 Knowledge and Science Town, Fakori Blvd., Mashhad
City
 Mashhad
Province
 Razavi Khorasan
Postal code
 91778-99191
Approval date
 2016-11-06, 1395/08/16
Ethics committee reference number
 IR.MUMS.SP.1395.64

Health conditions studied

1

Description of health condition studied
 The Effect of Spirulina Platensis on fasting blood Glucose, Glycosylated Hemoglobin (HbA1c) and Lipid Profile in Type 2 diabetic Patients
ICD-10 code
 E11
ICD-10 code description
 Type 2 diabetes mellitus

Primary outcomes

1

Description
 The primary outcome is the change in hemoglobin beta-glycosylated (HbA1c) levels.
Timepoint
 The timing is measured at the beginning of the study and the days 30, 60, and 90 of the study.
Method of measurement
 Chromatography will be used to measure HbA1c.

Secondary outcomes

1

Description
 Fasting blood Glucose and Lipid Profile
Timepoint

The timing is measured at the beginning of the study and the days 30, 60, and 90 of the study.

Method of measurement

Blood glucose analysis and use of lipid profile kits

Intervention groups

1

Description

Intervention group: Patients enrolled in the study will be in control and intervention groups. In addition to conventional anti-diabetic treatment, the intervention group will receive Spirulina concentrate powder at a dose of 2 g / day (in two divided doses of 1 g / 12 hours and powders will be supplied in gelatin capsules of 500 mg). These patients are monitored for 90 days.

Category

Treatment - Drugs

2

Description

Control group: Patients enrolled in the study will be in control and intervention groups. The control group will receive conventional anti-diabetic treatment that has been prescribed and will receive placebo. These patients are monitored for 90 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghodsi Health Center

Full name of responsible person

Sousan Dolatabadi

Street address

Sanabad Avenue

City

Mashhad

Province

Razavi Khorasan

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9185837715

Phone

+98 51 3844 0077

Email

dolatabadis1@mums.ac.ir

Web page address

<http://behdasht3.mums.ac.ir/index.php/43-persian-category/229-ghodsi>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Ghoreishi building, Daneshgah Street Mashhad
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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Zhila Taherzadeh

Position

Associated Proffesor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

School of pharmacy, Pardis university campus, Park square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Zhila Taherzadeh

Position

Associated Proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

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Full name of responsible person

Javad Boskabadi

Position

Lack scientific grade - Pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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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