

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effects of oral administration of Spirulina Platensis (cultured Iranian) on blood glucose and glycosylated Hemoglobin blood in type II diabetes mellitus patients

Protocol summary

Summary

Objectives: The effect of oral administration of Spirulina Platensis (cultured Iranian type) on the blood glucose and glycosylated Hemoglobin in type II diabetes mellitus patients. Design: the participants will be selected from male and female type 2 diabetics admitted to the Diabetes Research Center (with the range of 30 to 60 years old, and 5-10 years history of oral anti-diabetic therapy). After completing the relevant questionnaire, at least 50 cases (non-randomized) with fasting blood glucose between 126-300 mgr/dl and HbA1c >7 mgr/ dl will be selected. However, smokers, patients with underlying diseases as well as pregnant and breastfeeding women will be excluded from the study. Setting and Intervention: The patients will be divided into two groups: a control group (only receiving oral anti-diabetic medications) and a treatment group who will receive Spirulina platensis powder concentrate 8 grams per day (In three divided doses every 8 hours) in addition to their previous treatment. These patients will be monitored for 90 days. Main Outcome Measures: The patients' blood glucose level will be measured (after 12 hours fasting) at 0, 30, 60 and 90 days after the intervention; their HbA1c levels will be recorded both at the beginning and at the end of study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052528067N1**
Registration date: **2016-08-22, 1395/06/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-22, 1395/06/01

Registrant information

Name

Hamideh Ghodrati azadi

Name of organization / entity

Ferdowsi University of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 3880 5631

Email address

ghodrati@um.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancelator for research of Ferdowsi University of Mashhad - Nano chemical cell company (Manufacturer and provider of Spirulina platensis powder)

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of oral administration of Spirulina Platensis (cultured Iranian) on blood glucose and glycosylated Hemoglobin blood in type II diabetes mellitus patients

Public title

Effect of Spirulina in the treatment of Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The age range of 30-60 years old; Type II Diabetic patients ; Disease duration 5-10 years ; Fasting blood glucose 126-300 milligram per deciliter ; Hemoglobin A1c more than 7
Exclusion criteria: Smoking; Develop other underlying medical condition ; Pregnancy and Breastfeeding

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is performed on patients of 10 diabetes centers in Mashhad by Non-random method .

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committees of Ferdowsi University of Mashhad and Mashhad University of Medical Sciences

Street address

pardis of Ferdowsi University of Mashhad, Azadi Square

City

Mashhad

Postal code

917751793

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

IR.MUMS.REC.1394.16

Health conditions studied

1

Description of health condition studied

Diabetes type2

ICD-10 code

IV

ICD-10 code description

E11

Primary outcomes

1

Description

Plasma glucose

Timepoint

0 and 30 days and 60 days and 90 days after intervention

Method of measurement

milligrams per deciliter by Autoanalyser

2

Description

Hemoglobin A1c

Timepoint

At 0 and 90 days after intervention

Method of measurement

milligrams per deciliter by NycoCard

Secondary outcomes

1

Description

Liver function tests

Timepoint

every 3 month

Method of measurement

Auto analyzer kits

Intervention groups

1

Description

Treatment group will receive Spirulina concentrate powder, product of Nano chemical cell company, at dose of 8 grams in 3 divided dose per day for 3 months in addition to their previous drugs.

Category

Treatment - Drugs

2

Description

Control group receive their previous diabetes drugs.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid ghodsi health center in Mashhad

Full name of responsible person

Melika Beihaghi

Street address

Sanabad Street

City

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Faculty of Veterinary Medicine, Ferdowsi University of Mashhad , Azadi square

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Fax**Email**

melika.beihaghi@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ferdowsi University of Mashhad

Full name of responsible person

Hamideh Ghodrati Azadi

Street address

Faculty of Veterinary Medicine, Pardis of Ferdowsi University of Mashhad, Azadi square

City

Mashhad

Grant name

3

Grant code / Reference number

33219

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Ferdowsi University of Mashhad

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Melika Beihaghi

Position

Master of Sciences

Other areas of specialty/work**Street address**

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Hamideh Ghodrati Azadi

Position

Ph.D in Biochemistry

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

Name of organization / entity

Ferdowsi University of Mashhad

Full name of responsible person

Melika Beihaghi

Position

Clinical biochemistry (MSc)

Other areas of specialty/work**Street address**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty