

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of wheat germ consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and BDNF level in patients with type 2 diabetes

Protocol summary

Study aim

The aim of present study is to evaluate the effects of wheat germ consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and Brain-Derived Neurotrophic Factor (BDNF) level in patients with type 2 diabetes.

Design

This is a randomized, placebo-controlled, double-blind parallel-group clinical trial. Eighty participants will randomly allocated to receive wheat germ per day (n = 40) or placebo (n = 40).

Settings and conduct

All participants aged 30–65 years with type 2 diabetes diagnosis will recruited from Isfahan Endocrine & Metabolism Research Center (IEMRC), Isfahan, Iran. Subjects will stratified according to gender and age (two levels: 30-50 years and 50-65 years). Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist. Wheat germ and its placebos will in the same form of package and the patients and researcher will not aware of the content of the pack until the end of trial.

Participants/Inclusion and exclusion criteria

The cases will enrolled in the study if they met these inclusion criteria: 1) Willingness to participation in the study; 2) Diagnosis of diabetes in the last 5 years; 3) Body Mass Index (BMI) <35. Individuals with history of cancer, cardiovascular disease, renal, hepatic and thyroid disorders or using insulin or oral agents inducing insulin secretion will excluded.

Intervention groups

Individuals will randomly divided into two groups to receive 20 g wheat germ or placebo (bread powder) per day for 12 weeks.

Main outcome variables

Weight; Waist circumference; BMI; Hemoglobin A1C; Total cholesterol; Triglyceride; Low-density lipoprotein; High-density lipoprotein; BDNF; Malondialdehyde; Total antioxidant capacity; Systolic blood pressure; Diastolic blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040827N1**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Reza Amnai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 1378

Email address

r_amani@nutr.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of wheat germ consumption on anthropometric indices, lipid profile, glycemic indices, oxidative stress markers, mood and BDNF level in patients with type 2 diabetes

Public title

Effect of wheat germ consumption in treatment of diabetes

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Willingness to participation in the study
Diagnosis of diabetes in the last 5 years
Body mass index <35

Exclusion criteria:

Using insulin or oral agents inducing insulin secretion
Smoking
Pregnancy and lactation
Using anti-psychotic drugs
Taking antioxidant supplements within the past 3 months before the intervention
Having a history of cancer, cardiovascular disease, renal, hepatic and thyroid disorders

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A stratified randomized permuted block (with block size 4) will generated by an independent bio-statistician. Subjects will stratified according to gender and age (two levels: 30-50 years and 50-65 years). Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a trained nutritionist. Researchers will not informed about randomization process until completion of data analyses (concealment).

Blinding (investigator's opinion)

Double blinded

Blinding description

Wheat germ and its placebos (bread powder) will manufactured by Narin Company (Isfahan, Iran). All

wheat germ and its placebo powders will provided by Narin Company in prepacked boxes numbered for each patient according to the randomization sequence. Wheat germ and its placebos will in the same form of package and the patients and researcher will not aware of the content of the pack until the end of trial.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2018-05-27, 1397/03/06

Ethics committee reference number

IR.MUI.REC.1397.3.074

Health conditions studied**1****Description of health condition studied**

Type 2 Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Fasting blood sugar

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Colorimetric

2

Description

Hemoglobin A1C

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

High-performance liquid chromatography

3

Description

Insulin

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzyme-linked immunosorbent assay (ELISA)

Secondary outcomes

1

Description

Weight

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Digital scale

2

Description

Waist Circumference

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

non-stretching tape measure

3

Description

Systolic blood pressure

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Sphygmomanometer

4

Description

Diastolic blood pressure

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Sphygmomanometer

5

Description

Total cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

6

Description

Triglyceride

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

7

Description

Low density lipoprotein-cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

8

Description

High density lipoprotein-cholesterol

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Enzymatic method

9

Description

Brain derived neurotrophic factor

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

enzyme-linked immunosorbent assay (ELISA)

10

Description

Malodialdehyde

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

enzyme-linked immunosorbent assay (ELISA)

11

Description

Total antioxidant capacity

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

enzyme-linked immunosorbent assay (ELISA)

12

Description

Depression score

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Depression Anxiety and Stress Scales (DASS-21)

13

Description

Anxiety score

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Depression Anxiety and Stress Scales (DASS-21)

14

Description

Stress score

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Depression Anxiety and Stress Scales (DASS-21)

15

Description

Appetite

Timepoint

Before intervention and 12 weeks after intervention

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: 20 g/day wheat germ for 12 weeks. Wheat germ will manufactured by Narin Company (Isfahan, Iran).

Category

Treatment - Other

2

Description

Control group: 20 g/day placebo (bread powder) for 12 weeks. Placebo will manufactured by Narin company (Isfahan, Iran).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine & Metabolism Research Center

Full name of responsible person

Reza Amani

Street address

Korram Ave,

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 1378

Fax

+98 31 3668 1378

Email

r_amani@nutr.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Hezajarib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8138

Email

sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Reza Amani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Hezarjarib Ave.
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 1378
Email
r_amani@nutr.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Reza Amani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Hezarjarib Ave.
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 1378
Email
r_amani@nutr.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Reza Amani
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work

Nutrition
Street address
Hezarjarib Ave.
City
Isfahan
Province
Isfahan
Postal code
81746-73461
Phone
+98 31 3668 1378
Email
r_amani@nutr.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The collected deidentified for the primary outcome measure only will be shared.

When the data will become available and for how long

starting 12 months after publication.

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

The data will provide for educational use.

From where data/document is obtainable

Reza Amani PO Box: 81746-73461
r_amani@nutr.mui.ac.ir

What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

Comments