

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The effect of barley Savigh consumption on blood sugar in predibetic menopausal women, Gonabad-2020

Protocol summary

Study aim

Determining The effect of barley Savigh consumption on blood sugar in predibetic menopausal women

Design

A randomized controlled clinical trial with parallel, randomized groups

Settings and conduct

This study is conducted in community health centers of Gonabad city. Pre-diabetics in the intervention group receive 60 grams of barley savigh daily for 4 weeks. Before the intervention and at the end of weeks 2 and 4, fasting blood sugar and blood sugar two hours after food are checked.

Participants/Inclusion and exclusion criteria

Inclusion criteria include being pre-diabetic (fasting blood sugar between 100 and 125 or two hours after food between 140-199 mg / dL), menopause, age 45 to 65, no antidiabetic drugs, no disease Cardiovascular, renal, hepatic, thyroid, and blood pressure, and exclusion criteria include the need to start insulin therapy or hypoglycemic drugs, Lack of regular consumption of barley savigh and causing complications in the person.

Intervention groups

The intervention group includes pre-diabetic women who receive intervention in the form of barley savigh. The control group includes pre-diabetic women who are not treated.

Main outcome variables

Blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200929048880N1**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

khadije kamali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 5723 2883

Email address

kamali.kh@gmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of barley Savigh consumption on blood sugar in predibetic menopausal women, Gonabad-2020

Public title

The effect of barley Savigh consumption on blood sugar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pre-diabetic women (fasting blood sugar between 100

and 125 or blood sugar two hours after a food between 140 and 199 mg / dL Menopause(having amenorrhea for at least 12 months) Age 65-45 years No diabetes Do not take anti-diabetic drugs No cardiovascular, renal, hepatic, thyroid and hypertensive diseases No history of smoking, drugs or alcohol Literate to read and write No history of grain allergy Body mass index 19/8 to 29

Exclusion criteria:

Incidence of diabetes during the study period Need to start insulin therapy or blood sugar-lowering drugs during the study period Occurrence of stressful events during the study period Lack of regular consumption of barley savigh Complication of the individual Hospitalization during the intervention Failure to complete the nutrition and physical activity questionnaire Incidence of hypoglycemia during the intervention

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

By referring to the community health centers of Gonabad city, people with inclusion criteria are selected by easy sampling method. Individuals will be assigned to intervention and control groups using a randomized block-by-block method with random number table.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Next to the Asian Road

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2020-09-09, 1399/06/19

Ethics committee reference number

IR.GMU.REC.1399.070

Health conditions studied

1

Description of health condition studied

Pre-diabetes

ICD-10 code

R73.01

ICD-10 code description

Impaired fasting glucose

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

Initially and 2 and 4 weeks after the study

Method of measurement

Standards of medical diagnostic laboratories

2

Description

2 hour postprandial plasma glucose

Timepoint

Initially and 2 and 4 weeks after the study

Method of measurement

Standards of medical diagnostic laboratories

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Consumption of 60 grams of barley savigh (20 grams before each meal) for 4 weeks

Category

Treatment - Drugs

2

Description

Control group: does not receive any intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Community health centers of Gonabad city

Full name of responsible person

Khadije Kamali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

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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

Gonabad 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**

Gonabad University of Medical Sciences

Full name of responsible person

Khadije Kamali

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Gonabad University of Medical Sciences

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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