

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of oat bran supplementation on glycemic profile in patients with gestational diabetes

Protocol summary

Summary

This investigation is a randomized controlled clinical trial to determine the effect of OAT bran on blood glucose profile in gestational diabetes Mellitus. Inclusion criteria consists of: Eligible participants were 20-40 years singleton pregnant women with <34 weeks gestation, whose GDM were detected by an endocrinologist based on one-step approach, as proposed by the IADPSG, that is, fasting blood glucose \geq 92 mg/dl or one hour glucose after ingestion of 75 g glucose \geq 180 mg/dl, or two hour glucose \geq 153 mg/dl. Women with pre-gestational diabetes and chronic medical conditions including heart, kidney and gestational diseases or high blood pressure were excluded from the study. Other exclusion criteria included having celiac or allergic reactions to oat bran, lactation during the past three months, and unwillingness to follow the prescribed diet. This clinical trial was conducted on 90 women visiting the clinics that were randomly divided into two groups, control and intervention. Three modes treatment are (treatment with insulin, metformin, the treatment regimen). Patients treated with insulin and metformin after 2 weeks run-in which blood sugar is to achieve stability. All patients entering the study were randomly divided into two groups, control and intervention. Interventions in the control group will receive only diet based on ADA individuals in addition to diet control, 30 grams of Oat bran daily receive weather. At the beginning and end of the study, weight, glucose, glucose 2 hours after a meal, fructosamine and HbA1C is measured. According to the doctor if the patient is in need of special treatment the patient is excluded (but not including insulin)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112720114N1**

Registration date: **2015-06-09, 1394/03/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-09, 1394/03/19

Registrant information

Name

Maedeh Shahzeidi

Name of organization / entity

Shahid Sadooghi University of Medical Sciences and Health

Country

Iran (Islamic Republic of)

Phone

+98 35 3624 0691

Email address

m.shahzeidi.nutr@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Shahid Sadooghi University of Medical Sciences and Health

Expected recruitment start date

2014-12-07, 1393/09/16

Expected recruitment end date

2015-07-06, 1394/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of oat bran supplementation on glycemic profile in patients with gestational diabetes

Public title

The effects of oat bran supplementation on glycemic profile in patients with gestational diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Eligible participants were 20-40 years singleton pregnant women with <34 weeks gestation, whose GDM were detected by an endocrinologist based on one-step approach, as proposed by the IADPSG, that is, fasting blood glucose ≥ 92 mg d⁻¹ or one hour glucose after ingestion of 75 g glucose ≥ 180 mg d⁻¹, or two hour glucose ≥ 153 mg d⁻¹(19). Women with pre-gestational diabetes and chronic medical conditions including heart, kidney and gestational diseases or high blood pressure were excluded from the study. Other exclusion criteria included having celiac or allergic reactions to oat bran, lactation during the past three months, and unwillingness to follow the prescribed diet

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single 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 the University of Medical Sciences

Street address

Imam Reza integrated, Blvd student, Yazd

City

Yazd

Postal code

8916189165

Approval date

2014-11-26, 1393/09/05

Ethics committee reference number

179475

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

gestational diabetes

ICD-10 code

O24

ICD-10 code description

Diabetes mellitus in pregnancy

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

FBS

Timepoint

Before Intervention and four week after Intervention

Method of measurement

enzymatic method, mg/dl

2**Description**

Fructose amin

Timepoint

Before Intervention and four week after Intervention

Method of measurement

enzymatic method, mg/dl

3**Description**

HbA1C

Timepoint

Before Intervention and four week after Intervention

Method of measurement

enzymatic method, mg/dl

4**Description**

2hhp

Timepoint

Before Intervention and four week after Intervention

Method of measurement

enzymatic method, mg/dl

5**Description**

Weight

Timepoint

Before Intervention and four week after Intervention

Method of measurement

scale, kg

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group consumed 30 grams of oat bran of the lunch and dinner with 100 grams of yogurt and a diet consistent with ADA

Category

Treatment - Other

2

Description

The control group consumed 100 grams of yogurt in lunch and dinner and a diet consistent with ADA

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Imam Ali

Full name of responsible person

Prof. Azade Najarzadeh

Street address

Navab safavi Bolvar, Yazd

City

Yazd

2

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Prof. Azade Najarzadeh

Street address

Bahonar Square, Yazd

City

yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Prof. Azade Najarzadeh

Street address

Department of Health, Imam Reza building, Student Blvd, Imam Hossein Square

City

yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd Shahid Sadoughi University of Medical Sciences

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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

dr Azade Najarzade

Position

PhD in Nutrition

Other areas of specialty/work

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Maedeh Shahzeidi

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Other areas of specialty/work

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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