Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥ 92 mg/dl or one hour glucose after ingestion of 75 g glucose ≥180 mg/dl, or two hour glucose ≥ 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

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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
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Person responsible for updating data

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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