Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

The effect oats bran on gestational Diabetes

Protocol summary

Study aim
The effect oat bran on gestational diabetes
Design
A clinical trial with a control group، Randomized quadruple block type، no blinded
Settings and conduct
Samples are selected from the 17 Shahrivar Health Center and the Women's Clinic of Imam Khomeini Hospital, which are 24 to 28 weeks pregnant, requiring 75 grams of dietary testing. Individuals are divided into two groups: one group receiving oat bran and one standard diet and the control group receiving only treatmenstandad
Participants/Inclusion and exclusion criteria
Having an abanormal bloiod sample in 75g glucose test, pregnant women 24-28 weeks. no login: Diabetes manifest, kidney and mental, liver disease
Intervention groups
The intervention group was given the standard broth with standard diet, And the control group received only standard diet
Main outcome variables
Fasting BLood Suger; Fasting Blood Suger 2 hours later

General information

Reason for update
Acronym
teobgd
IRCT registration information
IRCT registration number: **IRCT20191220045828N1**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**
Registration date
2020-04-18, 1399/01/30

Registrant information

Name
Zahra Barati
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-02-04, 1398/11/15
Expected recruitment end date
2020-06-04, 1399/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect oats bran on gestational Diabetes

Public title
Oats bran on Gestationl Diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Example of having a cell phone Having even a disturbed blood sampel (blood glucose of one hour 180 and above and two hours of 153mg/dl and above) after consuming glucose 75g Pregnant women 24-28 weeks Reading and writing skills Observe the standard diet Age 18 to 35 years Fasting blood sugar between 93 and125
Exclusion criteria:
A history of overt diabetes in person Diseases that disrupt the research procecess:liver diseas, kidney,

psychological, stroke sensitivityto oat bran history of stillbirth, gestational diabetes, birth of the macrosome baby family history of diabetes

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **112**
More than 1 sample in each individual
Number of samples in each individual: **56**
There are 56 people in each group

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method is randomized 4 block design.The present study will be conducted as a randomized clinical trial.Patients will be assigned to intervention and control groups using a randomized block design with 4 block.The research setting will be the Imam khomeini hospital in ahvaz

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
Ahvaz University of Medical Sciences

Street address
Ahvaz University of Medical Sciences

City
Ahvaz

Province
Khouzestan

Postal code
15794-61357

Approval date
2020-01-19, 1398/10/29

Ethics committee reference number
IR.AJUMS.REC.1398.784

Health conditions studied

1

Description of health condition studied
Gestational Diabetes

ICD-10 code
O24.410

ICD-10 code description
Gestational diabetes mellitus in pregnancy, diet controlled

Primary outcomes

1

Description
Gestational diabetes

Timepoint
Before intervention, After intervention

Method of measurement
Blood suger test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After the necessary explanations about the method and objectives of the study, diabetic pregnant women who should receive a standard diet, in addition to the standard diet training by the doctor, will consume oatmeal bran from the OAB factory. And their blood sugar will be monitored after consuming oat bran. And oat bran is eaten one to three tablespoons a day for a month at lunch and dinner.

Category
Lifestyle

2

Description
Control group: Women who have gestational diabetes and will only receive a standard diet.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Women clinic of Imam Khomeini Hospital in Ahvaz

Full name of responsible person
Zahra Barati

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Women clinic of Imam Khomeini Hospital in Ahvaz

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Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Ahvaz 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
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Masters student
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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