

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Dec 2021

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 treatment standad

Participants/Inclusion and exclusion criteria

Having an abnormal blood 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 Sugar; Fasting Blood Sugar 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

Country

Iran (Islamic Republic of)

Phone

+98 61 3447 8421

Email address

zara.barati2017@gmail.com

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 Gestational Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Example of having a cell phone Having even a disturbed blood sample (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 and 125

Exclusion criteria:

A history of overt diabetes in person Diseases that disrupt the research process: liver diseases, kidney,

psychological, stroke sensitivity to 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

Khuzestan

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 sugar 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

Street address

Women clinic of Imam Khomeini Hospital in Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6315733653

Phone

+98 61 3733 8358

Email

zara.barati2017@gmail.com

2**Recruitment center****Name of recruitment center**

Shahrivar Health Center Ahvaz

Full name of responsible person

Zahra Barati

Street address

Shahrivar Health Center , Thirty meters, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3733 3138

Email

Zara.barati2017@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badvi

Street address

Ahvaz University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6315733653

Phone

+98 61 3373 8383

Email

badvi-m@ajums.ac.ir

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**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Barati

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School Nursing and Midwifery, Ahvaz University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6195893774

Phone

+98 61 3733 1338

Email

zara.barati2017@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mina Iravani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery

City

Ahvaz

Province

Khouzestan

Postal code

6195893774

Phone

0098613738331

Email

Minairavani2004@yahoo.com

Person responsible for updating data

zara.barati2017@gmail.com

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Barati

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School Nursing and Midwifery, Ahvaz University of
Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

098 6137331338

Email

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