Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of receiving rice bran on the severity of nausea and vomiting during pregnancy in women referred to comprehensive health service centers in Gonabad city - 2023

Protocol summary

Study aim

Determining the effect of rice bran intake on the severity of nausea and vomiting of pregnancy in women referring to comprehensive health service centers in Gonabad city

Design

The clinical trial has two parallel intervention and control groups, single-blind with a sample size of 72 people, who are assigned to two intervention and control groups by the available sampling method and with random blocks of 4.

Settings and conduct

After screening and determining the mothers suffering from nausea and vomiting of pregnancy, the intervention group will be given 10 grams of rice bran packets to consume for one week, twice a day before lunch and dinner or with yogurt. The control group uses odorless white flour in the same way as the intervention group. Both groups complete the Rudders questionnaire every night for a week.

Participants/Inclusion and exclusion criteria

Age 18-35 years, gestational age under 20 weeks, desired pregnancy, singleton fetus, live and natural, not using assisted reproductive methods to get pregnant, not suffering from chronic diseases, not having a high-risk pregnancy, not having severe and adverse events in 3 Last month, suffering from mild or moderate nausea and vomiting of pregnancy based on the standard criteria of Rhodes, not using chemical drugs or complementary medicine to control and treat nausea and vomiting of pregnancy since 3 days before the start of the study, not being allergic to rice bran

Intervention groups

The intervention and control groups were given 10 gram packets of rice bran and white flour, respectively, for one week, 2 times a day before lunch or dinner, or with yogurt.

Main outcome variables

Severity of nausea and vomiting of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230221057481N1**
Registration date: **2023-02-24, 1401/12/05**
Registration timing: **prospective**

Last update: **2023-02-24, 1401/12/05**
Update count: **0**

Registration date

2023-02-24, 1401/12/05

Registrant information

Name

Fereshteh Haghighat khah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4212 0161

Email address

frshthhqyqt4@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-04, 1402/01/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of receiving rice bran on the severity of nausea and vomiting during pregnancy in women referred to comprehensive health service centers in Gonabad city - 2023

Public title
The effect of rice bran intake on the severity of nausea and vomiting during pregnancy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in research Ability to read and write Age 18-35 Gestational age below 20 weeks based on the first day of the last menstrual period or ultrasound Desired pregnancy Single fetus, alive and natural Not using assisted reproductive methods to get pregnant No drug use Not suffering from chronic diseases and psychiatric disorders based on the mother's statements Not having a high-risk pregnancy Absence of serious and adverse events in the last 3 months Having mild or moderate nausea and vomiting of pregnancy based on the Rhodes standard criteria Not using chemical drugs or complementary medicine to control and treat nausea and vomiting of pregnancy from 3 days before the start of the study Insensitivity to white rice, brown rice and rice bran based on the person's statements

Exclusion criteria:
Unwillingness to continue cooperation Occurrence of medical and midwifery problems The occurrence of severe and adverse events Severe nausea and vomiting based on the Rhodes questionnaire or nausea and vomiting with a cause other than pregnancy based on the diagnosis of a gynecologist Use of chemical drugs or complementary medicine to control and treat nausea and vomiting of pregnancy during the study period Allergy to rice bran used in the study Not using rice bran correctly or not using it for more than one day Failure to complete questionnaires or incomplete completion

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign the samples to each of the 2 intervention and control groups, blocks of 4 variables are used. In this way, first, 6 possible states of blocks of 4 are listed and a number from 1 to 6 is assigned to each block. Then a number between 1 and 6 is randomly selected and then people are assigned to the test (A) and control (B) groups based on the block corresponding to the selected number

Blinding (investigator's opinion)
Single blinded

Blinding description
Rice bran and white flour without fiber (placebo) are packed by the researcher in identical envelopes in terms of shape and size and coded with A and B codes; And the study will be blinded to the participants

Placebo
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
On the side of Asian Road, Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
9691793718

Approval date
2023-02-21, 1401/12/02

Ethics committee reference number
IR.GMU.REC.1401.172

Health conditions studied

1

Description of health condition studied
Nausea and vomiting of pregnancy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Severity of nausea and vomiting of pregnancy

Timepoint
Before starting the intervention and during the intervention for one week

Method of measurement
Rhodes Standard Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For a week, every day, 2 times a day, they consume a 10 gram package of rice bran before lunch and dinner or with yogurt.
Category
Treatment - Drugs

2

Description
Control group: For a week, every day, twice a day, they consume a 10 gram package of white flour before lunch and dinner or with yogurt.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive health service centers of Gonabad city
Full name of responsible person
Fereshteh Haghighat Khah
Street address
On the side of Asian Road, Gonabad University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Roghaieh Rahmany
Street address
On the side of Asian Road, Gonabad University of Medical Sciences
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roghaiehrahmany@yahoo.com
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
Fereshteh Haghighat Khah
Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Fereshteh Haghighat Khah

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The participants are coded to increase access to them and their information, but at the time of publication, only the main result is published and the information of the participants is not published in any way.
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Access is open to the public
Under which criteria data/document could be used
If people have a request, without mentioning the coding of the information confidentially, without the personal information of the people, only the main and side results will be provided to the requester.
From where data/document is obtainable
E-mail
What processes are involved for a request to access data/document
First, the applicant sends a message to the e-mail and explains the reason for using the data, and within a week, information with conditions and restrictions will be sent to the applicant.
Comments