

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Study of Cardamom powder effect on the severity of nausea and vomiting in pregnant women referred to health centers in Chalus city 1389-90

Protocol summary

Summary

The objective of the study is to determine the effect of cardamom powder on the severity of nausea and vomiting in pregnant. The researcher going to the selected health centers, will complete PUQE (pregnancy unique questionnaire) questionnaire for pregnant women 6 to 22 weeks with nausea and vomiting and then, researcher will select 120 between them eligible volunteers that be signed the consent form. The prenatal care will be provided to women. The samples will be divided into placebo and cardamom powder groups (60 samples in each group). In cardamom powder group, capsules containing 500 mg of powdered cardamom and in placebo group, capsules containing 500 mg lactose will be prescribe three times daily for 4 day. The participants will complete the PUQE questionnaire 2 times daily during intervention. At the end of intervention, researcher will complete the final questionnaire. Then, during and after intervention will be analyzed the severity of nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107016928N1**

Registration date: **2011-08-03, 1390/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-03, 1390/05/12

Registrant information

Name

mansoureh Gharaiagh Zandi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2387 2206

Email address

s.zandi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2011-06-22, 1390/04/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of Cardamom powder effect on the severity of nausea and vomiting in pregnant women referred to health centers in Chalus city 1389-90

Public title

Study of Cardamom powder effect on the severity of nausea and vomiting in pregnant women referred to health centers in Chalus city 1389-90

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Research units are Iranian and they have literacy in reading and writing; Singleton and normal pregnancy with 6 to 22 weeks based on LMP and ultrasound; Not having molar pregnancy; Not having symptoms of Threatened abortion; Not having acute

Pyelonephritis; Not having Thyroid dysfunction; Not having identified digestive diseases which may cause nausea and vomiting; having a normal pregnancy based on documents that be existing in health centers; Having mild to moderate nausea and vomiting without hyperemesis gravidarum symptoms; Not to use anti emetic or emetic drugs(herbal or chemical drugs); Not to use tobacco; Not having psychological problems and unpleasant event over 6 months ago according to pregnant women reporting; Not unexpected pregnancy according to pregnant women reporting. Exclusion criteria: Not taking two courses of drug or more and to use anti emetic herbal or chemical drugs during study; Having Threatened abortion; Having spotting and severe nausea and vomiting which is required to treatment; Having Cardamom powder consumption in daily diet.

Age

From **15 years** old to **44 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Tabnak Ave, Evin, Chamran highway, Tehran, Iran, Islamic Republic Of

City

Tehran

Postal code

Approval date

2011-05-01, 1390/02/11

Ethics committee reference number

89-01-86-7624-1

Health conditions studied

1

Description of health condition studied

nausea and vomiting of pregnancy

ICD-10 code

R11

ICD-10 code description

Mild Hyperemesis gravidarum, mild or unspecified, starting before the end of the 22nd week of gestation

Primary outcomes

1

Description

Severity of nausea and vomiting of pregnancy

Timepoint

Before, during and after intervention

Method of measurement

Modified pregnancy- unique quantification of Emesis/ Nausea(PUQE)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Cardamom powder capsules 500 mg, three times a day orally for 4 days.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsules 500 mg contained Lactose, three times a day orally for 4 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Prenatal clinic of Razy hospital in Chalus city

Full name of responsible person

Hossein Ahmadi- Clinic manager

Street address

Razy hospital, Opposite Koorosh St, Chalus/ Noshahr Ring road, Chalus.

City

Chalus

2

Recruitment center

Name of recruitment center

Alavicola health center.

Full name of responsible person

Maryam Shabani.Midwife

Street address

Alavicola St, Emam Reza Blvd, Chalus.

City

Chalus

3

Recruitment center

Name of recruitment center

The health center NO.2(Bazar rooz).

Full name of responsible person

Mrs. Sam.Midwife

Street address**City**

Chalus

4

Recruitment center

Name of recruitment center

The health center NO.1(Farhang).

Full name of responsible person

Dr. Hossein khajvand. Head of center

Street address**City**

Chalus

5

Recruitment center

Name of recruitment center

Hachirood health center

Full name of responsible person

Mrs. Hosseinpoor.Midwife

Street address

Chalus, Hachirood.

City

Chalus

6

Recruitment center

Name of recruitment center

Taze abad health center

Full name of responsible person

Soheila Mansoori. Midwife

Street address

Taze Abad, Chalus.

City

Chalus

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Mohammad Rahmati Roodsari

Street address

Vice Chancellor for Research, Shahid Beheshti University of Medical Sciences, Next to Taleghani hospital, Tabnak Ave, Evin, Chamran highway, Tehran, Iran, Islamic Republic Of.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti 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**

Nursing and Midwifery Faculty, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Gity Ozgoli

Position

M.Sc in Midwifery Education & Academic Faculty Member

Other areas of specialty/work**Street address**

Nursing and Midwifery Faculty, Niaiesh Ave. & Valiasr Ave. junction, Above Vanak Square, Valiasr Ave, Tehran.

City

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

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Web page address

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