

# 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**

Tehran

**Postal code****Phone**

+98 21 8820 2512

**Fax****Email**

gozgoli@yahoo.com

**Web page address**

## Person responsible for scientific 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 & Resaercher

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 8820 2512

**Fax**

**Email**

gozgoli@yahoo.com

**Web page address**

**Person responsible for updating data**

**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 & Resaercher

**Other areas of specialty/work**

**Street address**

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

**City**

Tehran

**Postal code**

**Phone**

+98 21 8820 2512

**Fax**

**Email**

gozgoli@yahoo.com

**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*