

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison effects of Chamomile, Ginger and Vitamin B6 on nausea and vomiting due to pregnancy

#### Protocol summary

##### Summary

(1) Objectives: The study aims to compare the effects of Chamomile, Ginger and Vitamin B6 on nausea and vomiting during pregnancy, (2) Design: This triple-blind randomized trial includes 105 pregnant women in 6-20 weeks of gestational age who suffer from weak or moderate nausea and vomiting, who will attend the Health Centers in Qazvin city, Iran, between 2015-2016, (3) Setting and Conduct: the researcher will go to Health Centers every day and apply randomized sampling between pregnant women with gestational age 6-20 weeks who suffer from mild or moderate nausea and vomiting. The Subjects will be selected randomly and divided into three groups of 35 patients including intervention group1 (green balls), intervention group2 (blue balls) and intervention group3 (red balls), (4) Major eligibility criteria: Participants are pregnant women with single fetus 6-20 weeks who suffer from mild or moderate nausea and vomiting induced by pregnancy. The following will be excluded from the study: women with severe nausea and vomiting who will be needed to be hospitalized and those who will be allergic to Ginger, (5) Intervention and experiment : Ginger capsules were given to group 1, Chamomile capsules were given to group 2, and vitamin B6 were given to group 3, the participants used them for 4 days. Then Rhodes index questionnaire was given to all participants to be completed before and after intervention, (6) Main outcome measures: Intensity and the number of times participants will experience nausea and vomiting before and after intervention will be measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201512011113N3**

Registration date: **2016-12-18, 1395/09/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-18, 1395/09/28

##### Registrant information

###### Name

Fatemeh Ranjkesh

###### Name of organization / entity

Qazvin University Of Medical Sciences, Nursing & Midwifery school

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 1335 9501

###### Email address

franjkes@qums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences Barij Esans Company

##### Expected recruitment start date

2016-01-21, 1394/11/01

##### Expected recruitment end date

2016-11-21, 1395/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison effects of Chamomile, Ginger and Vitamin B6 on nausea and vomiting due to pregnancy

##### Public title

Effect of Chamomile, Ginger and Vitamin B6 on nausea and vomiting due to pregnancy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Women with single fetus 6-20 weeks; mild or moderate nausea and vomiting induced by pregnancy, Exclusion criteria: Women with severe nausea and vomiting ; those who will be allergic to Ginger.

**Age**

From **19 years** old to **35 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **105**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Triple blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomized clinical trial

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Qazvin University of Medical Sciences

**Street address**

Bahonar Boulevard, Qazvin University of Medical Sciences

**City**

Qazvin

**Postal code**

34197-59811

**Approval date**

2015-10-04, 1394/07/12

**Ethics committee reference number**

IR.QUMS.REC.1394.178

**Health conditions studied****1****Description of health condition studied**

Nausea and Vomiting during pregnancy

**ICD-10 code**

O21.0

**ICD-10 code description**

Mild hyperemesis gravidarum

**Primary outcomes****1****Description**

The intensity and frequency of nausea and vomiting

**Timepoint**

Before and after the intervention

**Method of measurement**

Rhodes index questionnaire

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The intervention 1: In group 1, Ginger capsules 250 mg will be consumed three times for 4 days and the intensity and frequency of nausea and vomiting before and after intervention will be measured with Rhodes index questionnaire

**Category**

Treatment - Drugs

**2****Description**

The intervention 2: In group 2, Chamomile capsules 250 mg will be consumed three times for 4 days and the intensity and frequency of nausea and vomiting before and after intervention will be measured with Rhodes index questionnaire

**Category**

Treatment - Drugs

**3****Description**

The intervention 3: In group 3, Vit B6 capsules 25 mg will be consumed three times for 4 days and the intensity and frequency of nausea and vomiting before and after intervention will be measured with Rhodes index questionnaire

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Health Centers in Qazvin City

**Full name of responsible person**

Fatemeh Ranjkesh  
**Street address**  
**City**  
Qazvin

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Barij Esans Company  
**Full name of responsible person**  
Fatemeh Ranjkesh  
**Street address**  
Vali Asr Squarer  
**City**  
Qazvin  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Barij Esans Company  
**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**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for scientific

## inquiries

### Contact

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## Person responsible for updating data

### Contact

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## 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*