

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
Fatemeh Ranjkesh
Position
Instructor/ Msc in Midwifery
Other areas of specialty/work
Street address
Vali Asr Squarer
City
Qazvin
Postal code
34197-59811
Phone
+98 28 3333 6001
Fax
Email
fatemehranjkesh@yahoo.com; franjkesh@qums.ac.ir
Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Ranjkesh
Position
Instructor/ Msc in Midwifery
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences
City
Qzvin
Postal code
34197-59811
Phone
+98 28 3333 6001
Fax
Email
fatemehranjkesh@yahoo.com; franjkesh@qums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Ranjkesh
Position
Instructor/Msc in Midwifery
Other areas of specialty/work
Street address
Qazvin University of Medical Sciences
City
Qazvin
Postal code
Phone
Fax
Email
fatemehranjkesh@yahoo.com; franjkesh@qums.ac.ir
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