Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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, between2015-2016, (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 fro 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 Scienes, Nursing & Midwifery school

Country

Iran (Islamic Republic of)

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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 Boulevar, 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 consumped 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 consumped 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 capsules25 mg will be consumped 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

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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