

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Assessment of the effect of a product of "Punica granatum" fruit and " mentha spicata" on nausea and vomiting in pregnancy

Protocol summary

Registration timing: **registered_while_recruiting**

Summary

One of the treatments for nausea and vomiting of pregnancy in traditional medicine is combination of the pomegranate and mint. The aim of this study is to evaluate the effect of pomegranate fruit and mint for nausea and vomiting of pregnancy with moderate intensity. The study population are 70 pregnant women aging 18- 40 years at 6-16 weeks of pregnancy, singleton pregnancy with live fetus based on ultrasound, moderate nausea and vomiting of pregnancy, Patient Satisfaction, ability to read and write, at least 24 hours before the visit did not take anti-nausea drug; exclusion criteria: severe nausea and vomiting during pregnancy, nausea and vomiting of pregnancy by secondary causes, multiple pregnancy, ectopic pregnancy, mole, presence of pregnancy complications such as bleeding and threatened abortion, history of chronic disease; that are randomly divided into two groups with block randomization method. The duration of treatment in both groups is one week, and one week follow-up. The intervention group receives a syrup of "Punica granatum" fruit and " mentha spicata", 5 cc, three times a day after meals and 20mg Vitamin B6 pills, three times a day before meals and the control group receives 20mg Vitamin B6 pills, three times a day before meals. General information, the severity and duration of their nausea, the number of vomiting and retching, and a history of other diseases will be collected. PUQE (The Pregnancy-Unique Quantification of Emesis scale) is used to assess the symptoms before, one and two weeks after interventions. A Visual Analogue Scale is used to assess the severity of symptoms.

Last update:

Update count: **0**

Registration date

2015-11-20, 1394/08/29

Registrant information

Name

Shahrbanoo Abdolhosseini

Name of organization / entity

Faculty of Traditional Medicine, Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Karmen University of Medical Sciences

Expected recruitment start date

2015-09-15, 1394/06/24

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of a product of "Punica granatum" fruit and " mentha spicata" on nausea and vomiting in pregnancy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022221186N1**

Registration date: **2015-11-20, 1394/08/29**

Public title

Effect of "Punica granatum" fruit and " mentha spicata" on nausea and vomiting in pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-40 years, gestational age 6-16 weeks, singleton pregnancy with live fetus based on ultrasound, moderate nausea and vomiting of pregnancy (7-13 score of PUQE 24 Questionnaire), Patient Satisfaction, the possibility follow-up the patient, ability to read and write, at least 24 hours before the visit did not take anti-nausea drug. Exclusion criteria: severe nausea and vomiting during pregnancy that may require fluid therapy and hospitalization, nausea and vomiting of pregnancy by secondary causes: peptic ulcer, hepatitis, pyelonephritis,... multiple pregnancy, ectopic pregnancy, mole, presence of pregnancy complications such as bleeding, threatened abortion, history of chronic disease, history of drug addiction, alcoholism and smoking, history of drug allergy.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Kerman University of Medical Sciences

Street address

jomhori High way. Kerman

City

Kerman

Postal code**Approval date**

2015-09-09, 1394/06/18

Ethics committee reference number

IR.KMU.REC.1394.232

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

nausea and vomiting of pregnancy

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

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

severity of nausea

Timepoint

Before, one week during intervention and one week after intervention

Method of measurement

VAS (Visual Analogue Scale)

2**Description**

Nausea time

Timepoint

Before intervention, one week during intervention and one week after intervention

Method of measurement

PUQE 24 hours questionnaire

3**Description**

vomiting times

Timepoint

Before intervention, one week during intervention and one week after intervention

Method of measurement

PUQE 24 hours questionnaire

4**Description**

Retching times

Timepoint

Before intervention, one week during intervention and one week after intervention

Method of measurement

PUQE 24 hours questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: syrup of Pomegranate fruit and Mentha spicata, Prepared in the herbarium of Institute of History of Medicine, Islamic and Complementary Medicine Iran University of Medical Sciences, 5 cc three times a day after meals for one week with Vitamin B-6 20 mg tablet three times daily before meals for one week

Category

Treatment - Drugs

2

Description

Control group: Vitamin B-6 20 mg tablet (Production of pharmaceutical company Ramvfarmyn Tehran) three times daily before meals for one week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health care centers of Iran University of Medical Sciences

Full name of responsible person

Shahrbanoo Abdolhosseini

Street address

Shahryar district Health System, Jihad ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Traditional Medicine, Traditional Medicine Research Center, Kerman University of Medical S

Full name of responsible person

Dr Abass Pardakhty

Street address

Central organization of Kerman University of Medical Sciences, after shafa crossroad, Jomhori ave, Kerman Kerman, Iran

City

Kerman

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Faculty of Traditional Medicine, Traditional Medicine Research Center, Kerman University of Medical S

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

Faculty of Traditional Medicine, Kerman University of Medical Sciences

Full name of responsible person

Shahrbanoo Abdolhosseini

Position

Ph.D. student in Traditional Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of Me

Full name of responsible person

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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