Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

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 are70 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015022221186N1**

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

Registration timing: **registered_while_recruiting**

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)

Phone

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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 vomitting in pregnancy

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, Jahad 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
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Full name of responsible person
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Person responsible for scientific inquiries

Contact
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Department of Traditional Medicine, School of Traditional Medicine, Shahid Beheshti University of Me
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Person responsible for updating data

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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