Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of "Cydonia Oblonga" fruit product with B6 on nausea and vomiting in pregnancy

Protocol summary

Summary

"Cydonia Oblonga" fruit or "Quince" is used for treatment of nausea and vomiting of pregnancy in Iranian Traditional Medicine. This clinical trial has been designed to assess this effect and compare "Cydonia Oblonga" with Vit-B6 in treatment of mild to moderate nausea and vomiting during pregnancy. The study population are 90 pregnant women aging 18- 40 years at 6-14 weeks of pregnancy, with pregnancy induced nausea and vomiting without any secondary causes. They will be assigned to two groups with Simple random sampling. Group I receives a product from "Quince" in the form of syrup consuming 1 table spoon three times a day before meals for one week and Group II receives 20mg Vitamin B6 pills, three times a day before meals for one week. General information and current and previous pregnancies information, their history of nausea, vomiting and retching in pregnancy, the severity of their nausea, 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 and one week 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: **IRCT2012081110559N1**
Registration date: **2013-03-03, 1391/12/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-03-03, 1391/12/13

Registrant information

Name
Efat Jafari Dehkordi
Name of organization / entity
Faculty of Traditional Medicine, Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 5515 2192
Email address
e-jafarid@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1- Vice chancellor for research Traditional Medicine Faculty of Tehran University of Medical Sciences 2- Research Institute for Islamic and Complementary Medicine, Tehran University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2013-08-19, 1392/05/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of "Cydonia Oblonga" fruit product with B6 on nausea and vomiting in pregnancy

Public title

Effect of "Cydonia Oblonga" fruit on nausea and vomiting in pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 18-40 years, gestational age 6-14 weeks, singleton pregnancy with live fetus based on ultrasound, mild to moderate nausea and vomiting of pregnancy (13 > score of PUQE 24 Questionnaire ≥ 6) 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, pancreatitis, cholecystitis, appendicitis, gastroenteritis, UTI, CNS disorders, gasteroesophageal reflux disease, hyperthyroidism, 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, and at least 48 hours before presentation anti- nausea medication (B6, Metoclopramide, etc.) are not used

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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization will conducted by the table of random number

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of the Research Institute for Islamic and Complementary Medicine, (Tehran Universit

Street address

No: 9, Pirnia Alley, Lalehzar St., Jomhury Ave., Tehran, Iran Tehran Tehran Iran, Islamic Republic Of

City

Tehran

Postal code

Approval date

2012-10-09, 1391/07/18

Ethics committee reference number

733/پ 26 /م ط

Health conditions studied

1

Description of health condition studied

Nausea and vomiting induced by pregnancy

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes

1

Description

Nausea

Timepoint

Before, one week and two weeks after intervention

Method of measurement

PUQE 24 hours Questionnaire and VAS (Visual Analogue Scale)

2

Description

Vomiting

Timepoint

Before, one week and two weeks after intervention

Method of measurement

PUQE 24 hours Questionnaire and VAS (Visual Analogue Scale)

3

Description

Retching

Timepoint

Before, one week and two weeks after intervention

Method of measurement

PUQE 24 hours questionnaire and VAS (Visual Analogue Scale)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: syrup of Quince fruit, 1 table spoon three times a day before meals for one week Control: Vitamin B-6 20 mg tablet three times daily before meals for one week

Category

Treatment - Drugs

2

Description
control: Vitamin B-6 20 mg tablet three times daily before meals for one week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital Complex, Vali-asr Hospital
Full name of responsible person
Efat Jafari Dehkordi
Street address
Imam khomeini Hospital complex, Vali-asr Hospital, Bagher khan Ave., Tehran, IRAN
City
Tehran

2

Recruitment center
Name of recruitment center
Private clinic of Mrs.Soodabe Bioos
Full name of responsible person
Efat Jafari Dehkord
Street address
City

3

Recruitment center
Name of recruitment center
Islamshahr District Health System
Full name of responsible person
Effat Jafari Dehkordi
Street address
City
Islamshahr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotuhi
Street address
Deputy of research of Tehran University of Medical Sciences, Ghods Ave., Keshavarz Blvd., Tehran, IRAN
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tehran University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Research Institute for Islamic and Complementary Medicine, (Tehran University of Medical Sciences)
Full name of responsible person
Ashrafeddin Goushegir
Street address
No: 9, Pirnia Alley, Lalehzar St., Jomhury Ave., Tehran, Iran Tehran Tehran Iran, Islamic Republic Of
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Institute for Islamic and Complementary Medicine, (Tehran University of Medical Sciences)
Proportion provided by this source
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, Tehran University of Medical Sciences
Full name of responsible person
Efat Jafari Dehkordi
Position
Ph.D. student in Traditional Medicine
Other areas of specialty/work
Street address
Faculty of Traditional Medicine, Behesht St., Vahdat Eslami Ave., Tehran, IRAN
City

Tehran
Postal code
Phone
+98 21 5569 3520
Fax
Email
e-jafarid@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Traditional Medicine, Tehran University of Medical Sciences
Full name of responsible person
Efat Jafari Dehkordi
Position
Ph.D. student in Traditional Medicine
Other areas of specialty/work
Street address
Faculty of Traditional Medicine, Behesht St., Vahdat Eslami Ave., Tehran, IRAN
City
Tehran
Postal code
Phone
+98 21 5569 3520
Fax
Email
e-jafarid@razi.tums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Faculty of Traditional Medicine, Tehran University of Medical Sciences
Full name of responsible person
Efat Jafari Dehkordi
Position
Ph.D. student in Traditional Medicine
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City
Tehran
Postal code
Phone
+98 21 5569 3520
Fax
Email
e-jafarid@razi.tums.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