

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 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  $\geq$  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, gastroesophageal 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 be 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 University)

**Street address**

No: 9, Pirnia Alley, Lalehzar St., Jomhuri 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**

ط م / 26 پ 733

**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 Dehkordi

##### 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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Faculty of Traditional Medicine, Tehran University of Medical Sciences  
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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*