Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of "Quince" (CydoniaOblonga) product and vitamin B6 for treatment nausea and vomiting of pregnancy.

Protocol summary

Study aim
Determining and comparing the severity of nausea, frequency of vomiting and frequency of burping in two groups of users of the product "Quince" product and vitamin B6

Design
A clinical trial with two intervention groups with parallel randomized groups was conducted on 120 patients in a simple randomization manner.

Settings and conduct
The first group was given one tablespoon of fruit product 3 times a day and the second group were given 20 mg of vitamin B6 three times a day for one week, and the variables were recorded by the patient every day based on a questionnaire. The severity of the disease before and after the treatment, the effectiveness of the treatment and the rate of recurrence of symptoms one week after the end of the treatment were re-examined in both groups. Sampling was done in Taleghani hospital clinic.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-40 Years GA of 6-16 week Singleton pregnancy with a live and healthy fetus Mild and moderate pregnancy nausea and vomiting Reading and writing literacy No Severe nausea and vomiting of pregnancy that requires hospitalization. N/V have not been caused by a cause other than pregnancy. N/V caused by a cause other than pregnancy. Multiple pregnancy, EP and multiple moles rolled out. Do not have pregnancy complications such Abortion. There is no history of chronic disease, addiction, smoking and drug allergy. They have not taken anti emetic medication in the 48 hours before visit.

Intervention groups
This product is prepared as a paste from fruit and is completely herbal and does not have any special side effects. Therefore, one group was given a common medicine for the initial treatment of pregnancy nausea, vitamin B6, and the other group was given a paste product.

Main outcome variables
Severity of nausea and vomiting; duration of nausea and vomiting; frequency of vomiting; frequency of burping; amount of sleep; appetite

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20231030059899N1**
Registration date: **2024-03-14, 1402/12/24**
Registration timing: **retrospective**

Last update: **2024-03-14, 1402/12/24**
Update count: **0**

Registration date
2024-03-14, 1402/12/24

Registrant information
Name
zahra Torkamani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-22, 1399/05/01
Expected recruitment end date
2021-01-20, 1399/11/01
Actual recruitment start date

2020-09-22, 1399/07/01

Actual recruitment end date

2021-01-20, 1399/11/01

Trial completion date

2021-02-14, 1399/11/26

Scientific title

Comparison of the effectiveness of "Quince" (CydoniaOblonga) product and vitamin B6 for treatment nausea and vomiting of pregnancy.

Public title

Investigating the effect of Quince fruit product for treatment nausea and vomiting of pregnancy.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnant woman with a healthy fetus With a gestational age of 6 to 16 weeks With mild to moderate nausea and vomiting Not taking anti emetic medication in the last 48 hours No history of specific disease Literacy for reading and writing

Exclusion criteria:

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Actual sample size reached: **91**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization of the individual has been done, based on the clients, one person will receive the common treatment of vitamin B6 and the next person will be given the fruit product.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Arabi Ave، Velenjak

City

Tehran

Province

Tehran

Postal code

1995711151

Approval date

2023-10-24, 1402/08/02

Ethics committee reference number

IR.SBMU.MSP.REC.1402.391

Health conditions studied

1

Description of health condition studied

Hyperemesis Gravidarum

ICD-10 code

021.0

ICD-10 code description

Hyperemesis gravidarum, mild or unspecified, starting before the end of the 22nd week of gestation

Primary outcomes

1

Description

Severity of nausea and vomiting

Timepoint

Measure improvement over two weeks on days 4 and 11

Method of measurement

Measurement of improvement based on PUQE-24 and severity based on VAS scoring system

2

Description

Duration of nausea and vomiting

Timepoint

Measure improvement over two weeks on days 4 and 11

Method of measurement

Measurement of improvement based on PUQE-24 and severity based on VAS scoring system

3

Description

Frequency of vomiting

Timepoint

Measure improvement over two weeks on days 4 and 11

Method of measurement

Measurement of improvement based on PUQE-24 and severity based on VAS scoring system

4

Description

Frequency of retching

Timepoint
Measure improvement over two weeks on days 4 and 11
Method of measurement
Measurement of improvement based on PUQE-24 and severity based on VAS scoring system

5

Description
Amount of sleep
Timepoint
Measure improvement over two weeks on days 4 and 11
Method of measurement
Measurement of improvement based on PUQE-24 and severity based on VAS scoring system

6

Description
Appetite
Timepoint
Measure improvement over two weeks on days 4 and 11
Method of measurement
Measurement of improvement based on PUQE-24 and severity based on VAS scoring system

Secondary outcomes

empty

Intervention groups

1

Description
Control group: patients were given vitamin B6 tablets
Category
Treatment - Drugs

2

Description
Intervention group: And it was given Quince product to the intervention
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Taleghani educational and therapeutic hospital
Full name of responsible person
Zahra Torkamani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Web page address
https://sbmu.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
80
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Torkamani
Position
Gynecologist
Latest degree
Medical doctor
Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data can potentially be shared after de-identifying individuals in an Excel file

When the data will become available and for how long
This file is now accessible

To whom data/document is available
It will be available for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
Only for scientific purposes and for the production of herbal products

From where data/document is obtainable
For information, contact Dr. Zahra Torkmani at phone number 09120728852 torkamanizahra330@gmail.com

What processes are involved for a request to access data/document
You will be informed as soon as you contact Dr. Torkmani

Comments