Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of quince sauce in preventing nausea and vomiting of pregnancy

Protocol summary

Study aim
Investigating the effect of quince sauce in preventing nausea and vomiting of pregnancy
Design
This was a controlled, parallel-group, randomized, phase 2 clinical trial conducted on 80 women with normal pregnancies and mild to moderate nausea and vomiting. The random allocation method of the permutation blocks was using Random Allocation software.
Settings and conduct
This study was conducted on 80 women with normal pregnancies and mild to moderate nausea and vomiting referred to Hazrat Zainab Hospital in Shiraz. Women were randomly assigned to receive quince sauce and routine anti-nausea treatment. Blinding was not performed for pregnant women.
Participants/Inclusion and exclusion criteria
Being in a state of singleton and normal pregnancy No molar pregnancy, twin pregnancy, and signs of threatened miscarriage, No thyroid dysfunction or any known gastrointestinal disease Mild to moderate nausea and vomiting symptoms No use of any herbal or chemical anti-nausea or emetic medication in the past twenty-four hours
Intervention groups
Intervention group (A) included pregnant women who were treated with quince sauce 10 mg three times a day for 7 days.
Main outcome variables
Nausea and vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241105063604N1**
Registration date: **2024-11-15, 1403/08/25**
Registration timing: **prospective**
Last update: **2024-11-15, 1403/08/25**
Update count: **0**
Registration date
2024-11-15, 1403/08/25

Registrant information
Name
Marzieh khezri
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3230 5884
Email address
mojtabaneydavoodi@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-11-21, 1403/09/01
Expected recruitment end date
2024-12-20, 1403/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of quince sauce in preventing nausea and vomiting of pregnancy

Public title
Investigating the effect of quince sauce in preventing nausea and vomiting of pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Being in a singleton, normal pregnancy where the gestational age is 6 to 22 weeks based on the first day of the last regular menstrual period or first trimester ultrasound. Absence of molar pregnancy, twin pregnancy, and signs of threatened miscarriage Absence of thyroid dysfunction and any known gastrointestinal disease No known illness that causes nausea and vomiting Mild to moderate nausea and vomiting Not taking any herbal or chemical anti-nausea or anti-emetic medication within the past twenty-four hours. No smoking

Exclusion criteria:

Severe nausea Failure to take two or more courses of medication or concurrent use of other anti-nausea medications, such as herbal or chemical anti-nausea medications Threatened miscarriage Allergy to quince sauce and andasterone and vitamin B6

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups (A and B). The random allocation method of permutation blocks will be performed using Random Allocation software. First, six different blocks will be created (ABBA, BABA, ABAB, BBAA, AABB and BABA) and one of these blocks will be randomly selected and, according to the order mentioned in the selected block, the patients will be divided into one of two groups (intervention) A or (control) B. Then, randomization will be performed for other patients as well. The intervention group (A) will include pregnant women who will be treated with quince sauce (made by the Faculty of Pharmacy, Shiraz University of Medical Sciences) for 7 days, 10 mg three times a day. The control group (B) will be prescribed the second drug andasterone and vitamin B6 for 1 tablet every 12 hours.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz, Zand Street, Central Building of University of Medical Sciences

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2024-08-22, 1403/06/01

Ethics committee reference number

IR.SUMS.MED.REC.1403.369

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

Nausea and vomiting of pregnancy

Timepoint

Before starting treatment and 7 days after starting treatment

Method of measurement

The second standard Rhodes Nausea and Vomiting Questionnaire was developed by Rhodes and McDaniel in 1999 and consists of 8 factors: the number, severity, and amount of vomiting, the number, duration, and severity of nausea, and the number and severity of retching, which are asked during the past 12 hours.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant women treated with quince sauce will receive 10 mg three times a day for 7 days.

Category

Treatment - Other

2

Description
Control group: Women treated with ondansetron and vitamin B6 for 1 tablet every 12 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zainab Hospital, Shiraz
Full name of responsible person
Marzieh Khezri
Street address
Holy Defense Intersection-Hazrat Zainab (PBUH) Educational and Therapeutic Center
City
Shiraz
Province
Fars
Postal code
7153813311
Phone
+98 71 3826 6811
Email
zeinabhp@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Hashem Hashempour
Street address
Zand Street, Central Building of University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3235 7282
Email
hashempurm@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Khezri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Zand Street - Faculty of Medicine
City
Shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3230 5884
Email
dr.marziehkhezri@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Marzieh Khezri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Zand Street - Faculty of Medicine
City
Shiraz
Province
Fars
Postal code
7134845794
Phone
+98 71 3230 5884
Email
dr.marziehkhezri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Marzieh Khezri

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Zand Street - Faculty of Medicine

City
Shiraz

Province
Fars

Postal code
7134845794

Phone
+98 71 3230 5884

Email
dr.marziehkhezri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The publication of any matter related to the research project must be coordinated with the Vice President for Research of Shiraz University of Medical Sciences.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available