Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Quince concentrated juice on severity of hyperemesis

Protocol summary

Study aim
Evaluation of Quince concentrated juice effectiveness on severity of hyperemesis
Design
Phase 3 double-blind randomized clinical trial with control group with placebo on 40 patients. for randomization, random allocation table was used.
Settings and conduct
This study was conducted in Mobini Hospital of Sabzevar. patients in intervention group received Quince concentrated juice and in control group received placebo.Two way blinding (researcher and participant) was done.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Primigravid women who are over 18 years old referring to Mobini Hospital of Sabzevar Singleton pregnancy Complaining from nausea and vomiting not caused by an underlying disease. Exclusion criteria: underlying disease that causes nausea and vomiting Known mental illness High risk of abortion History of infertility Multiple pregnancy
Intervention groups
Three times a day, one tablespoon of the Quince concentrated juice after each meal in the intervention group Three daily doses of placebo (combination of starch, water, sugar and food coloring) in the amount of one tablespoon after each meal in the control group.
Main outcome variables
Times of nausea/vomiting; severity of nausea/vomiting; ; duration of nausea/vomiting;

General information

Reason for update
Acronym
EQCJSH
IRCT registration information
IRCT registration number: **IRCT20240502061630N1**
Registration date: **2024-05-15, 1403/02/26**
Registration timing: **prospective**

Last update: **2024-05-15, 1403/02/26**
Update count: **0**
Registration date
2024-05-15, 1403/02/26

Registrant information
Name
Narjes Forouhar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 4223 5611
Email address
forouharn1@medsab.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-05-21, 1403/03/01
Expected recruitment end date
2024-08-22, 1403/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of Quince concentrated juice on severity of hyperemesis

Public title
Evaluation of the effect of Quince concentrated juice on severity of hyperemesis
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primigravid Over 18 YO Singleton pregnancy Low risk pregnancy

Exclusion criteria:

Underlying disease with nausea and vomiting Known mental disorder Threatened abortion History of infertility Multiple pregnancy

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be selected by available sampling method and will be divided into two intervention and control groups by random allocation method. The tables have random numbers in both row and column directions, and the numbers of the rows and columns are in five-digit blocks next to each other and in a separated form to facilitate its use. To select sample people from the table, the researcher randomly starts from a point of the table in the direction of row or column. He can choose the point by closing his eyes and placing his finger or pen tip on the table. But according to the type of codes (one-digit, two-digit, three-digit, etc.), he must choose the same number of digits in the direction of the row or column.

Blinding (investigator's opinion)

Double blinded

Blinding description

In addition to the usual anti-nausea and vomiting regimen, patients are given medication which non of patient or researcher know. Third person outside the research team identifies the medicine and placebo with A and B codes. patients enter groups A and B by lottery. At the end of the research, after the data analysis is done content of A and B will be revealed.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Sabzevar University of Medical Sciences

Street address

Sabzevar Medical Sciences Central Building, Asad Abadi St, Sabzevar City

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617213112

Approval date

2024-03-12, 1402/12/22

Ethics committee reference number

IR.MEDSAB.REC.1402.138

Health conditions studied

1

Description of health condition studied

Hyperemesis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hyperemesis

Timepoint

At the beginning of study and 8 weeks later

Method of measurement

Checklist

Secondary outcomes

1

Description

Duration of Hyperemesis

Timepoint

At the beginning of study and 8 weeks later

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 1 tablespoon of Quince concentrated juice TDS after every meal

Category

Treatment - Drugs

2

Description
Control group: Placebo containing of water, starch, sugar and eatable color,1 tablespoon of Quince concentrated juice TDS after every meal
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mobini Hospital of Sabzevar
Full name of responsible person
Narjes Forouhar
Street address
Kashefi St
City
Sabzevar
Province
Razavi Khorasan
Postal code
9613856776
Phone
+98 51 4422 1002
Email
Mobini.H@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Seyede Zahra Matloubi
Street address
Sabzevar University of Medical Sciences, Asadabadi St
City
Sabzevar
Province
Razavi Khorasan
Postal code
96133856776
Phone
+98 51 4407 8440
Email
info@medsab.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
Sabzevar University of Medical Sciences
Full name of responsible person
Narjes Forouhar
Position
Associate professo
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mobini Sabzevar Hospital, North Kashefi St, Sabzevar City
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8424
Email
forouharn1@medsab.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Narjes Forouhar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Mobini Sabzevar Hospital, North Kashefi St, Sabzevar City
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8424

Email
forouharn1@medsab.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Narjes Forouhar

Position
Associate professo

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Mobini Sabzevar Hospital, North Kashefi St, Sabzevar City

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913114

Phone
+98 51 4401 8424

Email
forouharn1@medsab.ac.ir

Sharing plan

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

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long
The access will begin from year 2026

To whom data/document is available
Everybody

Under which criteria data/document could be used
Sending request

From where data/document is obtainable
First, send your request to the e-mail address forouharn1@medsab.ac.ir and if there is no response, call the number below. 09153710581

What processes are involved for a request to access data/document
1 month

Comments