Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of K-K9 point acupressure and Quince and Ginger syrup on nausea and vomiting of pregnancy

Protocol summary

Study aim
Comparison of the effect of KN9 and ginger syrup on nausea and vomiting of pregnancy in pregnant women

Design
The present study is a randomized, single-blind clinical trial, which was conducted after obtaining an ethics permit with the code IR-GMU-REC.1401.009 from the ethics committee of Gonabad University of Medical Sciences on 44 pregnant women who referred to comprehensive health service centers in Gonabad It was done in in the year1402.

Settings and conduct
Individuals with the entry criteria and desired characteristics were selected as available and after obtaining written informed consent, they were randomly assigned to two groups. The method of blinding was that the pregnant mothers were asked not to tell the other mothers present in the study about the method used to reduce nausea and vomiting.

Participants/Inclusion and exclusion criteria
Single pregnancy, maternal age 18-40 years, gestational age less than 20 weeks, no high risk pregnancy, no illness with nausea and vomiting such as peptic ulcer, hepatitis, pyelonephritis, pancreatitis, cholecystitis, appendicitis, gastroenteritis, urinary tract infection, central nervous system disorders, esophageal reflux disease, hyperthyroidism, mental illness, lack of chronic diseases such as kidney disorders, hypertension, diabetes, nausea with or without Vomiting with mild and moderate severity (score 4-12 based on PUQE-24 questionnaire) of 24

Intervention groups
In one group, under the supervision of a specialist doctor, pregnant mothers were given Barij sorbet and ginger essential oil, prepared by Barij pharmaceutical company, and in the other group, mothers were given gentle pressure on the 9 K-K point for two minutes every two hours to the extent that they felt They brought it in for 4 days (days 4 to 7) so that they don't have any discomfort and it is tolerable.

Main outcome variables
Severe nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200720048144N3**
Registration date: **2024-08-07, 1403/05/17**
Registration timing: **retrospective**

Last update: **2024-08-07, 1403/05/17**
Update count: **0**

Registration date
2024-08-07, 1403/05/17

Registrant information
Name
Fatemeh Kameli
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-20, 1401/07/28

Expected recruitment end date
2023-01-02, 1401/10/12

Actual recruitment start date
2022-10-25, 1401/08/03

Actual recruitment end date

2023-01-02, 1401/10/12

Trial completion date

2023-01-02, 1401/10/12

Scientific title

Comparing the effect of K-K9 point acupressure and Quince and Ginger syrup on nausea and vomiting of pregnancy

Public title

Comparing the effect of K-K9 point acupressure and Quince and Ginger syrup on nausea and vomiting of pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Single pregnancy maternal age 18-40 years gestational age less than 20 weeks nausea with or without Vomiting with mild and moderate severity (score 4-12 based on PUQE-24 questionnaire) of 24

Exclusion criteria:

high risk pregnancy illness with nausea and vomiting such as peptic ulcer, hepatitis, pyelonephritis, pancreatitis, cholecystitis, appendicitis, gastroenteritis, urinary tract infection, central nervous system disorders, esophageal reflux disease, hyperthyroidism, mental illness Known insensitivity to extracts to ginger

Age

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

Gender

Female

Phase

1-2

Groups that have been masked

- Participant

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Pregnant mothers referring to community health service centers who meet the entry criteria and desired characteristics were selected as available. And after obtaining written informed consent, they will be randomly assigned in two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done in such a way that the pregnant mothers participating in the study will be asked not to tell the mothers in the opposite group about the method used to reduce their nausea and vomiting.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

Gonabad, near Asian Road, Gonabad University of Medical Sciences

City

gonabad

Province

Razavi Khorasan

Postal code

9691675781

Approval date

2022-04-11, 1401/01/22

Ethics committee reference number

IR.GMU.REC.1401.009

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

Severity of nausea and vomiting based on PUQE-24 questionnaire

Timepoint

before the start of the intervention and on the 8th day after the start of the intervention

Method of measurement

Questionnaire PUQE-24

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Intervention group: In one group, under the supervision of a specialist doctor, Sharbat Beh and Zanjabil Barij essential oil, prepared by Barij

Pharmaceutical Company, were given and the amount and method of consumption were taught to the mothers. So that on days 4 to 7, one tablespoon is consumed one hour before each meal. This syrup is a standardized 120 ml container based on 26-22 mg of total phenolics (in terms of gallic acid) per 5 ml of syrup and its ingredients include betel nut, ginger and honey.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: In the other group of mothers, from 7 am to 7 pm, every two hours for two minutes on the K-K point 9 (picture no. 1) gentle pressure to the extent that they do not feel uncomfortable and tolerable for 4 days (4 days) to 7) entered. The researcher taught mothers the exact location of the K-K9 point and the amount of pressure on it in a practical way.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

مراکز خدمات جامع سلامت شهر گناباد

Full name of responsible person

fateme kameli

Street address

مراکز خدمات جامع سلامت شهر گناباد

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Dr. Leila Sadegh Moghadam

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Gonabad. Side of Asian Road. Gonabad University of Medical Sciences

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

fateme kameli

Position

مربی هیئت علمی

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

fateme kameli

Position

Faculty instructor

Latest degree
Master
Other areas of specialty/work
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fateme afshari
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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