Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of using ice compresses on the neck area on nausea and vomiting in pregnant women referred to the University hospitals: A randomized clinical trial

Protocol summary

Study aim

The aim of the study is to determine the effect of ice compress on the intensity and frequency of nausea and vomiting and the amount of related medication use in pregnant women referring to selected hospitals of Tehran University of Medical Sciences.

Design

A randomized controlled clinical trial will be conducted on 148 pregnant women. Participants will be recruited by convenience sampling and allocated into two groups using block randomization with a block size of 4, and the study will be performed as a double-blind trial.

Settings and conduct

The study is conducted in selected hospitals. After informed consent, participants are assessed for eligibility and instructed on applying the ice pack to the posterior upper neck. Identical gel packs are used for 5 minutes, three times daily from days 2 to 8. Daily symptoms are recorded using the Rhodes Index

Participants/Inclusion and exclusion criteria

Participants were pregnant women aged 18–35 years, at 6–16 weeks of gestation, with singleton viable pregnancies and mild to moderate nausea and vomiting based on the Rhodes Index, and able to read and write. Exclusion criteria included severe nausea requiring treatment or hospitalization, hyperemesis gravidarum, related pathological conditions, and pregnancy termination

Intervention groups

In the intervention group, participants are trained to use an ice compress on the posterior upper neck between C1 and T1, and they apply it three times daily for 5 minutes each time for one week. In the control group, a similar cold compress with the same temperature of 0 to 4°C, duration of 5 minutes, and frequency of three times per day is applied to the non-dominant shoulder.

Main outcome variables

Intensity of nausea; frequency of nausea; intensity of vomiting; frequency of vomiting; number of anti-nausea and anti-vomiting medications used.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260514069399N1**
Registration date: **2026-06-03, 1405/03/13**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**
Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-04, 1405/06/13

Expected recruitment end date

2027-03-06, 1405/12/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of using ice compresses on the neck area on nausea and vomiting in pregnant women referred to the University hospitals: A randomized clinical trial

Public title
Effect of ice compresses on nausea and vomiting in pregnant women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of mild to moderate nausea and vomiting of pregnancy (NVP) based on a score of 1 to 32 on the Rhodes Index of Nausea, Vomiting, and Retching (RINVR). Women aged 18 to 35 years. Gestational age of 6 to 16 weeks based on a reliable Last Menstrual Period (LMP) or first-trimester ultrasound; confirmed singleton pregnancy with a normal viable fetus. Ability to read and write (Literacy).
Exclusion criteria:
Development of severe nausea and vomiting requiring hospitalization and/or use of any antiemetic or other medications beyond those prescribed by the study physician. Development of hyperemesis gravidarum (HG). Presence of other symptoms suggestive of a pathological cause of nausea/vomiting (e.g., diarrhea). Occurrence of any medical condition that may cause, worsen, or mimic nausea and vomiting (e.g., gastrointestinal infection, urinary tract infection, thyroid disorders, or other systemic illnesses), as judged by the study clinician. Pregnancy termination (miscarriage or elective termination).
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **148**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to the intervention or control group using block randomization. A fixed block size of 4 will be used to ensure balanced and uniform allocation between the two groups throughout the enrollment period. The random allocation sequence will be generated by an independent statistician using Random Allocation Software (RAS). The sequence will be created by randomly selecting and ordering all possible allocation permutations within four-participant blocks. To ensure allocation concealment, the generated randomization list will be placed in sequentially numbered, opaque, sealed, light-impermeable envelopes (SNOSE). Each envelope will be opened only at the time of participant enrollment and after baseline data collection. The investigator responsible for participant recruitment and enrollment will be blinded to the allocation sequence, and only the statistician responsible for randomization will have access to the master list.
Blinding (investigator's opinion)
Double blinded
Blinding description
To minimize bias and enhance the validity of the findings, this study is designed as a sham-controlled clinical trial, and blinding will be implemented as follows: 1) Participant blinding Participant blinding is achieved by applying a cold compress in both groups, with the only difference being the application site. In both groups, the type of compress (similar gel ice pack), temperature (0–4°C), contact duration (5 minutes), and frequency (three times daily) are identical. In the intervention group, the compress will be applied to the posterior upper neck, whereas in the control group it will be applied, with the same specifications, to the non-dominant shoulder (as a sham/control site with minimal expected physiological effect on nausea). Participants will not be informed which site is considered the “active therapeutic” site versus the “sham/control” site; therefore, they will remain blinded to group allocation. 2) Blinding of the enrolling/recruiting investigator The investigator responsible for recruitment, eligibility assessment, obtaining written informed consent, and baseline assessment will have no access to the randomization sequence. Group assignment will be implemented using sequentially numbered, opaque, sealed, light-impermeable envelopes (SNOSE). Each envelope will be opened only after eligibility confirmation and completion of baseline assessment. This procedure ensures allocation concealment and prevents selection bias. 3) Blinding of outcome assessor and data analyst The primary outcome will be measured using the Rhodes Index, completed as a self-report by participants. To further reduce assessment and analysis bias, the dataset will be provided to the assessor/analyst with groups coded as “Group A” and “Group B”, and statistical analyses will be conducted by an individual blinded to group identity. The allocation code will be disclosed only after the analyses are completed and finalized. 4) Data Safety Monitoring and writing team The randomization list will be kept by the statistician responsible for randomization. The analysis and writing team will have access only to coded data (A/B) until the statistical analysis is finalized, in order to minimize interpretive and reporting bias. 5) Ethical note All participants will be informed that they are taking part in a clinical trial and that they will receive one of the two study protocols. Blinding pertains only to whether the assigned application site represents the “active” intervention or the sham/control condition, and does not involve withholding information about research participation.
Placebo
Used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the School of Nursing and Midwifery and the School of Rehabilitation, Tehran Uni
Street address
Tohid Square, Dr. Mirkhani Street (Nosrat-e Sharghi), Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2026-05-31, 1405/03/10
Ethics committee reference number
IR.TUMS.FNM.REC.1405.040

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
The primary outcome variable is the severity of nausea and vomiting, assessed daily using the Rhodes Index (RINVR). This index quantifies subjective symptoms, providing a measurable outcome for intervention effectiveness.
Timepoint
Daily from day 2 to day 8 of the intervention
Method of measurement
The Rhodes Index of Nausea and Vomiting questionnaire consists of 8 five-option Likert-scale questions, completed over a 12 or 24-hour period. This self-administered tool measures:Severity of nauseaFrequency of nauseaNausea distress/discomfortFrequency of vomitingAmount of vomitingVomiting distress/discomfortFrequency of retchingRetching distress/discomfortThe tool separately measures objective and subjective aspects of nausea and vomiting. Patients complete this questionnaire by selecting one option, ranging from the least symptoms or absence thereof (score of zero) to the worst condition (score of 4). Consequently, the total score ranges from 0 to 32. A score of 0 indicates absence of symptoms, 1-8: mild, 9-16: moderate, 17-24: severe, and 25-32: very severe.This questionnaire was first used in pregnant women by Zhou et al. in 1996. The Rhodes Index of Nausea and Vomiting was translated for the first time by Norani et al. in 2000, and its content validity was assessed, establishing its validity for evaluating the severity of nausea and vomiting in pregnant women. Furthermore, the reliability of the tool was examined using the split-half method, yielding a correlation coefficient of 0.85 and a Cronbach's alpha coefficient of 0.89. Additionally, Modarres et al. reported a test-retest reliability of 0.75 in the population of pregnant women in 2012. In a study by Moradian et al. in 2014, the validity of the tool was examined in cancer patients undergoing chemotherapy, with a reported Cronbach's alpha of 0.88.

2

Description
Frequency of Nausea and Vomiting:The frequency of nausea refers to the number of times a patient experiences nausea within a 24-hour period. The frequency of vomiting refers to the number of times a patient vomits within a 24-hour period. Both are measured using the frequency-related questions within the Rhodes Index questionnaire.
Timepoint
Daily from day 2 to day 8 of the intervention
Method of measurement
The Rhodes Index of Nausea and Vomiting questionnaire consists of 8 five-option Likert-scale questions, completed over a 12 or 24-hour period. This self-administered tool measures:Severity of nauseaFrequency of nauseaNausea distress/discomfortFrequency of vomitingAmount of vomitingVomiting distress/discomfortFrequency of retchingRetching distress/discomfortThe tool separately measures objective and subjective aspects of nausea and vomiting. Patients complete this questionnaire by selecting one option, ranging from the least symptoms or absence thereof (score of zero) to the worst condition (score of 4). Consequently, the total score ranges from 0 to 32. A score of 0 indicates absence of symptoms, 1-8: mild, 9-16: moderate, 17-24: severe, and 25-32: very severe.This questionnaire was first used in pregnant women by Zhou et al. in 1996. The Rhodes Index of Nausea and Vomiting was translated for the first time by Norani et al. in 2000, and its content validity was assessed, establishing its validity for evaluating the severity of nausea and vomiting in pregnant women. Furthermore, the reliability of the tool was examined using the split-half method, yielding a correlation coefficient of 0.85 and a Cronbach's alpha coefficient of 0.89. Additionally, Modarres et al. reported a test-retest reliability of 0.75 in the population of pregnant women in 2012. In a study by Moradian et al. in 2014, the validity of the tool was examined in cancer patients undergoing

chemotherapy, with a reported Cronbach's alpha of 0.88.

Secondary outcomes

1

Description

Anti-emetic Medication Use:This outcome refers to any use of anti-emetic medication (prescribed by a physician or permitted self-administration) by patients during the study period. The recorded information includes the type and name of the drug, the dosage, the frequency of use per day, and the time and manner of administration. The objective is to investigate the patterns and overall extent of anti-emetic medication use in the intervention and control groups.

Timepoint

Daily throughout the intervention period (from day 2 to day 8). Information regarding daily medication use will be completed at the end of each day.

Method of measurement

n this clinical trial, the primary measurement instrument for the secondary outcome related to anti-emetic medication use is a Researcher-Developed Checklist, meticulously designed based on the study protocol and clinical considerations. This checklist serves as a structured and precise data collection tool, capturing comprehensive details regarding each instance of anti-emetic drug administration. The key columns within this checklist include: Type and Name of Drug: This section enables the participant to specify the exact name of the anti-emetic medication used (e.g., ondansetron, metoclopramide) and, where applicable, its dosage form (such as tablet, capsule, injection, suppository). This facilitates the differentiation and analysis of the efficacy of various medications. Dosage: Within this column, the precise quantity of the administered drug is recorded in standard units (e.g., milligrams, milliliters). This data is crucial for calculating cumulative dosage and comparing medication doses across different participants and throughout the study period. Frequency of Use per Day: This field is designed to tally the total number of times the medication was taken within a 24-hour period. Recording this variable provides insight into the patient's medication-taking pattern and their daily requirement for the drug. Time and Manner of Use: This component encompasses two distinct aspects:Time of Administration: Recording the specific time or time interval of drug intake during the day.Manner of Administration: Specifying the route by which the medication was administered (e.g., oral, intramuscular, intravenous, rectal suppository). This information can influence the onset and effectiveness of the drug.

Intervention groups

1

Description

Intervention group: In this clinical trial, following approval from the University Ethics Committee and receipt of the official sampling authorization, the researcher introduces the study objectives to pregnant women attending the selected centers who report nausea and vomiting of pregnancy. Eligible participants who meet the inclusion criteria and express willingness to participate provide written informed consent. Participants are then allocated to the intervention or control group using block randomization with a block size of four, generated by Random Allocation Software (RAS). The allocation sequence is placed in sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. Both the researcher responsible for enrollment and the final outcome assessor remain blinded to group assignments to minimize bias.At baseline, demographic and pregnancy-related information is collected, and potential confounding variables including dietary habits, history of nausea and vomiting in previous pregnancies, psychological status and anxiety, and anti-emetic medication use are recorded to be included as covariates in the final statistical analysis. On the first day of the study, participants undergo a medical examination to assess for skin lesions or anatomical abnormalities in the neck area and to evaluate physiological tolerance to cold exposure. Screening includes assessment for history of cold sensitivity, Raynaud's phenomenon, cold urticaria, peripheral vascular disorders, neuropathy, cardiovascular diseases exacerbated by cold, thyroid disorders, and cold-induced headaches. Individuals with contraindications are excluded from the study.Participants in the intervention group receive treatment with a standard gel ice compress maintained at a temperature of 0–4°C. Prior to each application, the compress is placed in a freezer at a constant temperature for 15 minutes. The intervention consists of applying the ice compress to the posterior upper neck region for exactly 5 minutes, three times daily (morning before breakfast, noon, and evening before sleep) from the second through the eighth day of the study. The application site is anatomically defined as the posterior upper neck, located between the base of the skull and the T1 vertebra, generally encompassing cervical vertebrae C1 to C7. The superior boundary extends to the occipital bone, the inferior boundary approximates the level of T1, and the lateral boundaries align with the sternocleidomastoid muscles. To ensure standardization and reproducibility, participants receive printed instructions with detailed anatomical illustrations, and standardized training is provided during the initial session. Participants use mobile phone timers to ensure precise five-minute applications and document adherence accordingly.Throughout the intervention period, the severity of nausea and vomiting is assessed daily using the Rhodes Index of Nausea, Vomiting, and Retching (RINVR). This validated instrument consists of eight five-point Likert-scale items (0–4) measuring severity, frequency, and distress related to nausea, vomiting, and retching over the previous 12 or 24 hours, with total scores ranging from 0 to 32. The instrument has demonstrated established validity and reliability in Iranian populations. Additionally, type, dosage, and frequency of anti-emetic medication use are recorded. The researcher maintains daily contact via phone calls or

text messages to reinforce adherence and provide support.Participants are continuously monitored for adverse events including cold-induced headache, dizziness, excessive numbness or burning, neck pain, and skin reactions. In cases of mild symptoms, the intervention is temporarily discontinued and resumed upon symptom resolution; persistent or severe symptoms prompt medical evaluation and possible withdrawal from the study. All adverse events are documented and reported according to ethical guidelines. Routine education on dietary and behavioral strategies to reduce nausea and vomiting is provided to all participants. The study design incorporates participant and assessor blinding to ensure methodological rigor and accurate evaluation of the therapeutic effect of the ice compress intervention.

Category

Treatment - Other

2

Description

Control group: Participants in the control group will use a similar compress (a standard gel ice compress maintained at 0–4°C), but the application site will differ from the intervention group. Prior to each application, the compress is placed in a freezer at a constant temperature for 15 minutes. The intervention consists of applying the ice compress for exactly 5 minutes, three times daily (morning before breakfast, noon, and evening before sleep) from the second through the eighth day of the study. The application site for the control group is the non-dominant shoulder. To ensure standardization and reproducibility, participants receive printed instructions with detailed anatomical illustrations, and standardized training is provided during the initial session. Participants use mobile phone timers to ensure precise five-minute applications and document adherence accordingly.Throughout the intervention period, the severity of nausea and vomiting is assessed daily using the Rhodes Index of Nausea, Vomiting, and Retching (RINVR). This validated instrument consists of eight five-point Likert-scale items (0–4) measuring severity, frequency, and distress related to nausea, vomiting, and retching over the previous 12 or 24 hours, with total scores ranging from 0 to 32. The instrument has demonstrated established validity and reliability in Iranian populations. Additionally, type, dosage, and frequency of anti-emetic medication use are recorded. The researcher maintains daily contact via phone calls or text messages to reinforce adherence and provide support.Participants are continuously monitored for adverse events including cold-induced headache, dizziness, excessive numbness or burning, shoulder pain, or skin reactions. In cases of mild symptoms, the intervention is temporarily discontinued and resumed upon symptom resolution; persistent or severe symptoms prompt medical evaluation and possible withdrawal from the study. All adverse events are documented and reported according to ethical research requirements. Routine education on dietary and behavioral strategies to reduce nausea and vomiting is provided to all participants. The study design incorporates participant and assessor blinding to ensure methodological rigor and accurate evaluation of the therapeutic effect of the ice compress intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women’s Comprehensive Hospital

Full name of responsible person

Dr. Ameneh Abeiri

Street address

Resalat Highway, after Shahid Bagheri Expressway, Shahid Baghdar Nia Street (Rashid North), corner of Alley 162 (Shahid Abdol Majid).

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ramin Kordi

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Keshavarz Boulevard, corner of Qods Street, Central Organization of the University, Sixth Floor, Deputy of Research and Technology.

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Azam Rahmani

Position
Associate Professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Associate Professor of Reproductive Health

Latest degree
Ph.D.

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Master’s student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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
De-identified Individual Participant Data (IPD), including demographic and clinical variables collected during the study, may be shared after completion of the trial. The full study protocol describing the objectives, design, methodology, and statistical analysis plan will be available. The statistical analysis codes and related instructions used for data analysis may also be provided upon reasonable request. A template of the informed consent form used in the study can be shared. The final clinical study report presenting the study findings will be available after completion of the study. In addition, the

data dictionary including definitions of variables and coding schemes used in the dataset will be accessible to interested researchers upon reasonable request.

When the data will become available and for how long

The study data and related documents will be available six months after the publication of the study results.

To whom data/document is available

Access to the study data and related documents will be provided to qualified researchers working in academic, clinical institutions.

Under which criteria data/document could be used

The data and related documents will be used solely for scientific research purposes, including reanalysis and secondary analyses, and in accordance with ethical guidelines and a data use agreement. Researchers will not be permitted to attempt re-identification of participants. All analyses must protect participant privacy and be conducted in accordance with approved study protocols.

From where data/document is obtainable

All requests for access to research data and related documents should be directed to Dr. Azam Rahmani. Email: azamrahmani7@gmail.com Address: Tohid Square, Dr. Mirkhani Street (Nosrat East).

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

Submission of a formal request including the research proposal and the intended analyses. Review of the request by the responsible investigator to determine eligibility. Signing of a data use agreement. Access to de-identified data and related documents will be provided within 4–6 weeks after approval of the request.

Comments

All shared data will be de-identified to ensure the privacy and confidentiality of participants. Users are required not to attempt to re-identify any participants.