

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparative Investigating the effect of the Auriculotherapy and mindfulness-based stress reduction counseling on the nausea and vomiting of pregnancy in pregnant women

Protocol summary

Study aim

Determining and comparing the effect of Auriculotherapy and mindfulness-based stress reduction counseling on pregnancy nausea and vomiting in pregnant women

Design

Clinical trial has control group, with parallel groups, one-blind, randomized, phase 2 on 159 patients. Used to randomization of R software.

Settings and conduct

After receiving a research license, the researcher learns the skills before starting the auriculotherapy, and after obtaining a degree and approval of the jurisdiction by the relevant specialist, it will begin to pregnant women referring to the clinics of the city of Lar. in the field of consultation and coordination Astadmshavr after offering them counseling sessions start Shvd.mtalh clinical trial is randomized. For blindness, the statistical advisor is unaware of what individuals belong.

Participants/Inclusion and exclusion criteria

1. Having a gestational age of 6-16 weeks on the first day of the last menstrual period
2. Mild or moderate vomiting nausea based on Rhodes index (score 8-24)
3. Dealing with complete physical and mental health (absence of gastrointestinal, heart or other underlying diseases)
4. Literacy to the extent of reading and writing
5. Having a single, normal, live, uncomplicated pregnancy and maintaining it until the end of the study
6. Women in the age range of 18 to 35 years
7. Willingness to participate in the study
8. Are you taking nausea and taking medications that may have side effects? Such as: metronidazole
9. Mole pregnancy is ruled out by ultrasound

Intervention groups

Three groups of 53 people are subjected to 15% drop in each group. Control group - Intervention with Auriculotherapy, Advisory intervention group with a stress-based stress approach

Main outcome variables

Reduce nausea and vomiting of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210728052005N1**

Registration date: **2021-09-06, 1400/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-06, 1400/06/15**

Update count: **0**

Registration date

2021-09-06, 1400/06/15

Registrant information

Name

Zahra Kashfi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5224 5533

Email address

zhrakashfi71@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparative Investigating the effect of the Auriculotherapy and mindfulness-based stress reduction counseling on the nausea and vomiting of pregnancy in pregnant women

Public title
Comparative Investigating the effect of the Auriculotherapy and mindfulness-based stress reduction counseling on the nausea and vomiting of pregnancy in pregnant women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having the gestational age of the last 6-16 weeks on the first day of the last menstrual period. Mild or moderate vomiting nausea based on Rhodes index (score 8-24) Having complete physical and mental health (absence of gastrointestinal, heart or other underlying diseases) 4. Literacy to the extent of reading and writing 5. Having a single, normal, live, uncomplicated pregnancy and maintaining it until the end of the study 6. Women in the age range of 18 to 35 years 7. Willingness to participate in the study 8. Failure to use drugs that may be subjected to nausea and vomiting. Like: Metronidazole. 9. Mole pregnancy is ruled out by ultrasound.
Exclusion criteria:
1) Loss of pregnancy 2) Reluctance to continue to participate in the study 3) Hospitalization due to the transformation of the disease into a severe form of hyperemesis gravidarum 4) Having any gastrointestinal disease or any disorder that leads to an abnormal increase in blood HCG levels (Twins) 5) Using other methods to treat nausea and vomiting in pregnancy, except anti-nausea pills

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

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **159**

Randomization (investigator's opinion)
Randomized

Randomization description
Because people enter the study over time, the blocking method of blocking is used. Which is used from statistical software. Because the three groups are in this study, six blocks are used.

Blinding (investigator's opinion)
Single blinded

Blinding description
In order to be blind, the statistical analyst would be

unaware of which group the subjects belonged to.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees
1
Ethics committee
Name of ethics committee
Ethics committee of Kerman University of Medical Sciences
Street address
Kerman University of Medical Sciences ,Medical University Campus ,Haft Bagh Highway ,Kerman ,Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2021-07-28, 1400/05/06
Ethics committee reference number
IR.KMU.REC.1400.237

Health conditions studied

1
Description of health condition studied
nausea and vomiting of pregnancy
ICD-10 code
ICD-10 code description

Primary outcomes

1
Description
Rhodes Nausea and Vomiting Questionnaire score
Timepoint
Rhodes questionnaire score was measured before the intervention, immediately after the intervention and two weeks after the intervention
Method of measurement
Rhodes Nausea and Vomiting Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Auriculotherapy .In the intervention group with Auriculotherapy, in addition to routine prenatal care and medication, for three consecutive weeks, every three to five days, Wakaria sids are attached to specific points (mouse, esophagus and master shoulder) of the mother's right ear. He is asked to press the labeled points five to six times a day for 60 seconds each time by applying pressure with his fingers.

Category

Treatment - Devices

2

Description

Intervention group: Mindfulness-based stress reduction counseling. In the counseling intervention group with a Mindfulness-based stress reduction approach, individuals will undergo six two-hour face-to-face sessions for three weeks (two sessions per week). It is noteworthy that due to the prevalence of Covid-19 disease and the importance of maintaining the health of pregnant women, if the conditions are not favorable until the intervention, counseling sessions will be taught virtually using the Skyroom training platform.

Category

Treatment - Other

3

Description

Control group: Routine Pregnancy Care. In the control group, while receiving routine pregnancy care, considering the ethical aspect of the research, it will be possible to use anti-nausea pills up to three times a day. It is important to note that the list will be provided to the mother and she will be asked to write down the name of the drug and its dosage to report to the researcher if she is taking a pill or treatment to reduce nausea and vomiting.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Saheb alzaman Clinic

Full name of responsible person

Dr.Rezaee

Street address

Shahr ghadim ,Modares Square

City

Lar

Province

Fars

Postal code

7431715544

Phone

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Email

zahrakashfi71@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.Abbas Pardakhti

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Fax

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Email

m.ghazanfarpour@kmu.ac.ir

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

zahra kashfi

Position

Master Student Of Counseling In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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No 5, Next to the Department of EducationLar, Shahr
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr.Masumeh Ghazanfarpour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Position

Msc Student

Latest degree

Bachelor

Other areas of specialty/work

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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

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

Yes - There is 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

Title and more details about the data/document

After the study, some information such as information about gestational age, the severity of vomiting nausea can be shared. More definite decisions will be made with the tutor.

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

After reading and printing the results, everyone will have access

Under which criteria data/document could be used

The use of research results by mentioning the names of the facilitator and colleagues for use in future studies will be allowed.

From where data/document is obtainable

zhrakashfi71@yahoo.com 00989124332581 zahra kashfi

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

Up to one month after the request, the authorized information will be sent to the person

Comments