Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparative Investigating the effect of the Auricolotherapy 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 uricolotherapy, 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

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zahrakashfi71@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 Auricolotherapy and mindfulness-based stress reduction counseling on the nausea and vomiting of pregnancy in pregnant women

Public title

Comparative Investigating the effect of the Auricolotherapy 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 hypermesis 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

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7431715544

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Dr.Abbas Pardakhti

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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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Person responsible for scientific inquiries

Contact

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Assistant Professor

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Other areas of specialty/work
Midwifery

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Bachelor

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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
zahrakashfi71@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