Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determining the effect of auricular acupressure on severity of nausea and vomiting in pregnancy among pregnant women referred to prenatal center of Arash Hospital

Protocol summary

Study aim
to evaluate the effect of auriculotherapy on nausea and vomiting during pregnancy.

Design
This study is a double blind randomized controlled clinical trial with parallel groups. sample of 64 individuals for each group was suggested accordingly

Settings and conduct
The research setting was the prenatal center of Arash Women's Hospital affiliated to Tehran University of Medical Sciences. patient and a statistics expert was blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria include mild to moderate nausea and vomiting according to Rhodes' Standard Index; women of 18 to 35 years old; in the 6th to 16th week of pregnancy based on the first day of last menstrual period or sonography; single pregnancy; and literacy. While exclusion criteria include severe nausea and vomiting; hyperemesis gravidarum during pregnancy; other symptoms such as diarrhea indicating pathologic nature of nausea and vomiting; and any other disease that causes or aggravates the symptoms of nausea and vomiting and results in abortion.

Intervention groups
the intervention started from day 3 and continued until day 6. On day 3, the researcher, at first, cleaned both outer auricles using 75% alcohol and then the effective areas in controlling nausea and vomiting such as Point zero, stomach, Sympathetic Autonomic, Shen Men, and cardia were determined and the researcher placed a magnetic seed on each point and adhered the seeds using non-latex glue. The participants were then instructed by the researcher to press each spot three times a day (morning, noon, and night) and each time for at least 30 seconds. The same was true for the participants in the sham control group except that the points where these magnetic seeds were placed (e.g. the vision, knee, shoulder and eyes) had no effects on the nausea and vomiting.

Main outcome variables
nausea and vomiting in pregnancy

General information

Reason for update
Closure of the study, the need for some modifications such as changing the study setting and blindness and also changing the name of the hospital

Acronym

IRCT registration information
IRCT registration number: **IRCT2015061415649N3**
Registration date: **2015-08-19, 1394/05/28**
Registration timing: **prospective**

Last update: **2020-01-29, 1398/11/09**
Update count: **1**

Registration date
2015-08-19, 1394/05/28

Registrant information

Name
Mohammad Eghbali

Name of organization / entity
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Recruitment status
Recruitment complete

Funding source
Vice chancellor for research, Tehran University of Medical

Sciences

Expected recruitment start date
2015-07-23, 1394/05/01
Expected recruitment end date
2016-07-22, 1395/05/01
Actual recruitment start date
2017-12-01, 1396/09/10
Actual recruitment end date
2018-10-01, 1397/07/09
Trial completion date
2019-02-19, 1397/11/30

Scientific title
Determining the effect of auricular acupressure on severity of nausea and vomiting in pregnancy among pregnant women referred to prenatal center of Arash Hospital

Public title
The effect of auricular acupressure on nausea and vomiting among pregnant women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
mild to moderate nausea and vomiting according to Rhodes' Standard Index the 6th to 16th week of pregnancy based on the first day of last menstrual period or sonography single pregnancy
Exclusion criteria:
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **128**
Actual sample size reached: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized block design with the size of 4 was used for randomization. The random sequence was proposed by a statistical expert and through appropriate software. A total number of 32 blocks of four were prepared and then the samples were assigned to intervention and sham control groups
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to observe the double-blindness of the study, sham points were used for patients in the sham control group so that individuals were unaware of which group they were assigned to. In addition, the statistics expert was unaware of the fact that which group was real and which were sham. Even those who were in charge of evaluation of the outcomes of the study were also unaware of the assigning of the individuals to real groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Science
Street address
Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733171
Approval date
2015-06-25, 1394/04/04
Ethics committee reference number
IR.TUMS.REC.1394.278

Health conditions studied

1

Description of health condition studied
Nausea & vomiting in pregnancy
ICD-10 code
O21.9
ICD-10 code description
تهوع و استفراغ بارداری

Primary outcomes

1

Description
Nausea and vomiting
Timepoint
Every night for 6 days
Method of measurement
Rhodes index

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, the magnetic seeds with a special adhesive latex will be attached in five effective points of ears for controlling the nausea and vomiting. Then patient will be asked for making pressure on each points for at least 30 seconds, three times a day
Category
Treatment - Other

2

Description
in the control group will be acted the same, but non effective points on nausea and vomiting will be used
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Prenatal center of Arash Hospital
Full name of responsible person
Mohamad Eghbali
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tehran University of Medical Sciences
Full name of responsible person
Doctor Masood Younesian - Vice President of Research and Technology
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Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods St, Keshavarz St, Tehran
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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
Vice chancellor for research, 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
University of Social Welfare and Rehabilitation Sciences
Full name of responsible person
Mohamad Eghbali
Position
PhD Student in nursing
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No decision has been made by the team at this time.

Study Protocol
No - There is not 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
No - There is not 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