

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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

Torbat Heydariyeh University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

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Sixth Floor, Central Organization of University, Qods St, Keshavarz Blvd

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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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Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran.

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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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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

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Name of organization / entity

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Sciences

Full name of responsible person

Mohamad Eghbali

Position

PhD Student in nursing

Latest degree

Ph.D.

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