Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Determining the effect of ear acupressure on the severity and occurrence of constipation and related quality of life during the pregnancy: A Double-Blind, Randomized Controlled Trial

Protocol summary

Study aim
Determining the effect of ear acupressure on the amount and severity of constipation and the quality of life related to it in pregnant women with constipation during pregnancy

Design
The clinical trial has an intervention and a control group, with parallel, double-blind and randomized groups, which will be conducted on 144 patients

Settings and conduct
This research will be conducted on pregnant women suffering from pregnancy constipation who refer to the prenatal center of Nohe-Day Hospital and Health Center in Torbat-E-Heydarieh. The participants are divided into two study groups using the random block method with blocks of size 4. In this study, the participants and the researcher will be blind as well.

Participants/Inclusion and exclusion criteria
Pregnant women aged 18-25 years; singleton pregnancy with normal and live embryo; wanted pregnancy; pregnancy constipation background based on ROME III index; being literate in reading and writing. Exclusion criteria: suffering from chronic constipation; digestive disorders; skin disease; infection and local lesion in the ear; recent use of pharmaceutical or non-pharmacological methods to reduce constipation; smoking

Intervention groups
Intervention group: In this group, effective points on constipation during pregnancy are stimulated by magnetic seeds using ear acupressure. These seeds remain in place for 7 days and are pressed by the person 8 times a day. Control group: ear acupressure will be performed in sham points for 7 days.

Main outcome variables
Constipation rate; severity of constipation; Quality of life-related to constipation, bristol stool form scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190625044009N2**
Registration date: **2024-04-19, 1403/01/31**
Registration timing: **prospective**

Last update: **2024-04-19, 1403/01/31**
Update count: **0**

Registration date
2024-04-19, 1403/01/31

Registrant information

Name
Mahla Rajabzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-04, 1403/02/15

Expected recruitment end date
2024-12-21, 1403/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the effect of ear acupressure on the severity and occurrence of constipation and related quality of life during the pregnancy: A Double-Blind, Randomized Controlled Trial

Public title
The effectiveness of ear acupressure on constipation and quality of life in pregnancy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women aged 18-35 years at any gestational age A singleton pregnancy with a normal and live embryo Wanted pregnancy Pregnancy constipation background based on the ROME III index Literacy No record of chronic constipation and digestive disorders, such as irritable bowel syndrome, anal fissure, rectal prolapse, intestinal obstruction and skin disease No record of infection and local lesion in the ear area No recent use of pharmaceutical or non-pharmacological methods to reduce constipation Not record of active or passive smoking

Exclusion criteria:
Suffering from chronic constipation, requiring medicine interventions (e.g., emollient, cassia, fig, hedge mustard, and Fusion herbal syrup) Digestive disorders, such as irritable bowel syndrome Psychological treatment history (medicine and mental treatment)

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **144**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized block design with a size of 4 was used for randomization. A total number of 36 blocks of four were prepared. Then, the samples were assigned to intervention and control groups. A specific letter is assigned to each group to construct the allocation sequence (A: Intervention Group, B: control Group). The allocation sequence will then be generated using online methods (https://www.sealedenvelope.com/simple-randomiser/v1/lists) without individual intervention. Next, the sequence is written on the sheets and placed in sealed envelopes, respectively to conceal the allocation sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
The random sequence will be provided to the main researcher and then based on the created sequence; each participant will be assigned to a particular group. Then, they will be placed in envelopes designed for this purpose, and each envelope will be numbered and closed. The person who is responsible for the implementation of the study will open the envelopes based on the number assigned to the patients and will perform the intervention based on the respective group. The person who is responsible for conducting the study is unaware of the type of intervention in the control and intervention groups. Since this intervention is performed in sham points for the control group, the patients are not informed of the nature of the allocated group.

Placebo
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 Sciences

Street address
Room 604, 6th floor, central building of Tehran University of Medical Sciences, intersection of Qods St., Keshavarz Blvd

City
Tehran

Province
Tehran

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1417653761

Approval date
2023-04-10, 1402/01/21

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1402.023

Health conditions studied

1

Description of health condition studied
Constipation in pregnancy

ICD-10 code
K59.0

ICD-10 code description
Constipation

Primary outcomes

1

Description

severity and occurence of Constipation

Timepoint

At the beginning of the study (before the intervention) and 7 days after the intervention

Method of measurement

Using the Constipation Assessment Scale for Pregnancy

2

Description

stool form

Timepoint

Before the intervention and during the intervention after each round of defecation is recorded

Method of measurement

Using the bristol stool form scale

Secondary outcomes

1

Description

Constipation quality of life

Timepoint

At the beginning of the study (before the intervention) and 7 days after the intervention

Method of measurement

Using the Constipation Quality of Life Scale

Intervention groups

1

Description

Intervention group: Both external earlobes are first cleaned with 75% alcohol, then the points of the rectum, large intestine, spleen, Shen Men and Senjia are determined and a magnetic seed is placed by the researcher in each point. Then the researcher teaches the patients to press the seeds 8 times a day for one minute each time. Pressing the points should be continued until they feel tingling or slight discomfort hese seeds remain in the constipation control points for 7 days and then removed

Category

Treatment - Other

2

Description

Control group: Both external earlobes are first cleaned with 75% alcohol; then, the points of vision, knee joint, eye, and shoulder joint (which do not have any effect on constipation) are determined. A magnetic seed is placed by the researcher in each point. Then, the researcher teaches the patients to press the seeds 8 times a day for one minute each time. Pressing should be continued until they feel tingling or slight discomfort. These seeds should remain in the constipation control points for 7 days and then removed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

9th Day hospital

Full name of responsible person

Zahra Nikfarjam

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Kashani Avenue, Torbat Heydariyeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

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
Torbate-Heidaria University of Medical Sciences

Full name of responsible person
Mahla Rajabzadeh

Position
Faculty instructor

Latest degree
Master

Other areas of specialty/work
Nursery

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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
Currently, no decision has been made in this regard by the team

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