

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Auriculotherapy on Sleep quality in pregnant women with Sleep disorder

Protocol summary

Study aim

Determining the effect of auricular therapy on sleep quality in pregnant women with sleep disorders

Design

Clinical trial with two groups of control and intervention with parallel groups, one-blind, randomized strain on 104 patients. Use envelopes for randomization will be.

Settings and conduct

This study will be performed in health centers affiliated to Tehran University of Medical Sciences. Intervention, performing auriculotherapy on the two groups of control and intervention will be that it is one-way blind (participants).

Participants/Inclusion and exclusion criteria

Inclusion criteria included: Willingness to participate in the study, Score 6 or more on the Pittsburgh Questionnaire, Women in the third trimester of pregnancy and the absence of medical diseases and complications of pregnancy. Exclusion criteria include: Reluctance to continue participating in the study, Not attending all auriculotherapy sessions, not even one session; Not doing exercises regularly; Pregnancy complications such as preeclampsia and other pregnancy complications during the study; Delivery of the pregnant mother before completing four sessions of auriculotherapy

Intervention groups

The intervention is as follows In 3 parts of the right ear (points: master shoulder/ lung1 and sleeping point), seed placed and these seeds are replaced every 7 days. The duration of the intervention period is 1 month and during this period, the seeds will be replaced 4 times. Women should press the seeds every 8 hours for 1 minutes. In the control group, instead of the seeds, only the seeds adhesives on the right ear (In 3 points of the throat, neck and sensory) women are placed.

Main outcome variables

sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210203050232N1**

Registration date: **2021-02-28, 1399/12/10**

Registration timing: **prospective**

Last update: **2021-02-28, 1399/12/10**

Update count: **0**

Registration date

2021-02-28, 1399/12/10

Registrant information

Name

Roghayeh Ghadimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 5554 7438

Email address

roghayehghadimi3@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

	The effect of Auriculotherapy on Sleep quality in pregnant women with Sleep disorder
Public title	Auriculotherapy in Sleep disorder
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Willingness to participate in the study Score 5 or more on the Pittsburgh Questionnaire Women in the third trimester of pregnancy Lack of medical diseases and pregnancy complications Exclusion criteria: Reluctance to participate in the study Score less than 5 on the Pittsburgh Questionnaire Women in the first and second trimesters of pregnancy
Age	No age limit
Gender	Female
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 104
Randomization (investigator's opinion)	Randomized
Randomization description	Sampling by randomized block design of two treatments with quadruple blocks: In this way, the letter A is considered for the intervention group and the letter B for the control group. Then we write all the permutation combinations of the letters A, A, B and B, which are 6 different combinations, on 6 cards as follows: 1. AABB , 2. ABBA , 3. ABAB , 4. BAAB , 5. BABA , 6. BBAA Then we randomly select a digit from 1 to 6 digits(with the help of a table of random numbers or we ask patient number one to choose a card at random). For example, if the number 2 was selected the meaning is that the first person in the intervention group will be the next two people in the control group and the fourth person in the intervention group. And we continue this operation until the sample size reaches the quorum.
Blinding (investigator's opinion)	Single blinded
Blinding description	Participants were aware of the general introduction of the study groups and will be kept blind only because they themselves are not aware of being in the intervention or control group. There seems to be no difference between the work done for the intervention and control groups (Auriculotherapy will be performed on both groups) and only the reader knows the difference between the groups.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Nursing and Midwifery and School of Rehabilitation, Tehran University of Medical Sciences

Street address

Simaye Iran

City

Tehran

Province

Tehran

Postal code

1816775733

Approval date

2020-12-01, 1399/09/11

Ethics committee reference number

IR.TUMS.FNM.REC.1399.149

Health conditions studied

1

Description of health condition studied

Sleep disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sleep disorder

Timepoint

Third Trimester of pregnancy

Method of measurement

Pittsburgh Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Auriculotherapy intervention will be performed for the members of the group which is placed on the three parts of the right ear (master shoulder, lung1and sleeping point) and will be for 4 weeks .Seeds will be replaced once a week. Samples should be pressed on the ear three times a day for one minute each time. Two and four weeks after the start of the intervention, the questionnaire will be completed by the

samples.
Category
Treatment - Devices

2

Description

Control group: Auriculotherapy will also be performed for the control group with the difference that in this group only glue (without seed) it will be placed on the right ear in three parts (sensory, throat and neck) for 4 weeks and if the adhesives are removed from the ear, they will be replaced. Two and four weeks after the start of the intervention, the questionnaire will be completed by the samples.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Baharloo Hospital
Full name of responsible person
Dr. Elham Ebrahimi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Gholam Hossein Rahimi Sherbaf
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Grant name

Vice Chancellor for Research, Tehran University of Medical Sciences

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
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
Tehran University of Medical Sciences
Full name of responsible person
Elham Ebrahimi
Position
Assistant Professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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