Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ariculotherapy 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 uriculotherapy 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 uriculotherapy

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

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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

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Position

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Latest degree

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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