Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

The effect of Auriculotherapy on stress and anxiety of legal abortion

Protocol summary

Study aim
Determining the effect of Auriculotherapy on stress and anxiety of legal abortion

Design
This two-group randomized controlled clinical trial study will be performed on 70 women who have referred for legal abortion. Random allocation software will be used for randomization.

Settings and conduct
This study will be performed on 70 women who have referred to Umm Al-Banin Hospital for legal abortion. In the intervention group, after obtaining the inclusion criteria and before starting the intervention, the Spielberger Anxiety and Stress Questionnaire (DASS-21) is filled out. Selected areas: My Sand / Heart / and Uterus (3 areas in total) are on both ears. The duration of applying pressure on each point is 30 seconds, a total of 3 minutes, and the amount of pressure is 1 kg.) With the applicator. One hour before and after the first round of orthocolotherapy with the applicator, the Spielberger and Stress Anxiety Inventory (DASS-21) will be completed.

Participants/Inclusion and exclusion criteria
Inclusion criteria include: willingness to participate in research, minimum literacy, age 35-38, gestational age less than 19 weeks, low-risk pregnancies, body mass index between 18.5 to 30, no alcohol and drug addiction, no History of treatment with uriculotherapy during the last 6 months, no sores or any lesions on the ear Conditions of non-entry: 7 days and cooperation, emergency patient due to bleeding and going to the operating room before the intervention, disposal of products before the end Intervention

Intervention groups
In the intervention group, two rounds of auricular therapy with a manual applicator (one hour before the start of misoprostol treatment and one hour after the start of misoprostol treatment) are performed by the researcher. In the control group, routine care is performed.

Main outcome variables
Stress rate score Anxiety rate score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211129053224N1**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date
2022-01-09, 1400/10/19

Registrant information

Name
afsaneh ghomiavili

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3522 3446

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ghomioa982@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-02, 1400/10/12

Expected recruitment end date
2022-05-19, 1401/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Auriculotherapy on stress and anxiety of legal abortion

Public title
The effect of Auriculotherapy on stress and anxiety of abortion

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18-35 years Minimum literacy Gestational age less than 19 weeks Willingness to participate in research and to have conscious satisfaction Low risk pregnancies Body mass index between 18.5 and 30 No history of treatment with Auriculotherapy during the last 6 months No sores or any lesions on the ear Contraindicated in Auriculotherapy Do not have a specific mental illness .Do not have severe medical disorders .No sores or any lesions (purulent papules, moles, skin inflammation) on the ear Do not have a history of taking certain medications.

Exclusion criteria:
Dissatisfaction and cooperate Emergency of the patient due to bleeding and going to the operating room before the intervention Disposal of products before the end of the intervention

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
. In this study, the permutation block method will be used to generate a sequence of random allocation of individuals to the study groups. Random allocation sequences will be performed using random allocation software and block size two. The permutation block method is one of the random allocation methods in which each block is selected according to the number of groups studied. In this study, there are two blocks, AB and BA. One of the blocks is randomly selected. If the first block, AB, is selected, the first person is assigned to group A and the second person to group B, and this process continues until all samples are allocated. The characteristic of this method is that the two study groups will have equal numbers.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the School of Nursing and Midwifery, Mashhad University of Medical Sciences

Street address
Khorasan Razavi, Mashhad, Daneshgah St., Ph.D. Crossroads, Ibn Sina St., School of Nursing and Midwifery

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2022-01-02, 1400/10/12

Ethics committee reference number
IR.MUMS.NURSE.REC.1400.076

Health conditions studied

1

Description of health condition studied
Stress

ICD-10 code
F43.0

ICD-10 code description
Acute stress reaction

2

Description of health condition studied
Anxiety

ICD-10 code
F41.9

ICD-10 code description
Anxiety disorder, unspecified

Primary outcomes

1

Description
Stress score

Timepoint
One hour before the first intervention, one hour after the first intervention, one hour before the second intervention and one hour after the second intervention

Method of measurement
Stress Questionnaire (DASS-21)

2

Description
Anxiety score
Timepoint
One hour before the first intervention, one hour after the first intervention, one hour before the second intervention and one hour after the second intervention
Method of measurement
Spielberger Anxiety Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
After selecting each research unit, the demographic information questionnaire, Spielberger anxiety questionnaire and stress questionnaire (DASS-21) for both intervention and control groups will be completed by the researcher. Selected areas: My Sand / Heart / and Uterus (3 areas in total) are on both ears. The duration of applying pressure on each point is 30 seconds, a total of 3 minutes and the amount of pressure is 1 kg. Massage time: (The first massage with the applicator one hour before the start of treatment with misoprostol and the second massage with the applicator one hour after the start of treatment with misoprostol) There are 2 massages with the applicator. One hour before and after the first round of echocardiography with the applicator, the Spielberger Manifest Obvious Anxiety and Stress Questionnaire (DASS-21) will be completed. Then, one hour after starting the treatment with misoprostol, the second round of auricular therapy with the applicator will be performed by the researcher. Also, one hour before and one hour after the second round of uriculotherapy, the Spielberger Anxiety and Stress Questionnaire (DASS-21) will be filled out by the researcher.
Category
Treatment - Other

2

Description
Control group: Routine care is performed in the control group.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Umm ol-Banin Hospital
Full name of responsible person
Dr. Fatemeh Tara
Street address
Ayatolah Bahjat
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9144734767
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Fax
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafqadi
Street address
University Street, Mashhad University of Medical Sciences
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Razavi Khorasan
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Phone
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Tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Mahin Tafazzoli

Position
Assistant Professor
Latest degree
Master
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The data will be shared after it becomes unidentifiable
When the data will become available and for how long
All researchers
To whom data/document is available
All researchers
Under which criteria data/document could be used
All women have an abortion license from a forensic center
From where data/document is obtainable
Email ghomioa982@mums.ac.ir Library of Mashhad School of Nursing to Mashhad, Daneshgah St.
What processes are involved for a request to access data/document
First, send a requested email and if you do not respond within a week, you can refer to the library of Mashhad School of Nursing.
Comments