

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

Email address

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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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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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
Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Student

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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