

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of auriculotherapy with electrical stimulation and seeds pressure on anxiety before colposcopy

Protocol summary

Summary

The purpose of this study is comparison the effect of auriculotherapy with electrical stimulation and seeds pressure on anxiety before colposcopy. In this clinical trial, after obtaining informed consent from 90 women eligible for colposcopy, which referred to educational hospitals in Mashhad, Samples will be selected by simple sampling method and then based on a random allocation method (using SPSS software) will be divided into three groups as control and two interventions. Inclusion criteria include: Age ≥ 18 years; do colposcopy for the first time; patient's consent to participate in this study; not being pregnant or lactating; the absence of lesion or rash at the ears. Exclusion criteria include: Unwillingness to continue cooperation; creating stressful events during the study; itching or inflammation and infection in the intervention group II. In the intervention group I (auriculotherapy with electrical stimulation) the researcher, will be applied (TAS) Transcutaneous auricular stimulation at 4 acupoints (Shenmen, Relaxation, Tranquilizer and Endocrine) with the Pointer Excel II and 2Hz frequency and 2mA Intensity, for 30 seconds on each acupoint. The electrical stimulation will conducted in 40 min before colposcopy on the two ears. Intervention group II (auriculotherapy with seeds) Researcher will attach the vaccariae seeds in place by a piece of opaque adhesive patch and fixed on to the same acupoints. The subjects will asked to press each point 60 seconds for three times a day. The auriculotherapy will conducted in the external ear on the non dominant side, for three days before doing colposcopy until colposcopy day. In the control group, Researcher will attach opaque adhesive patch without seed, at 4 non related points to anxiety, 3 days before colposcopy. In all groups anxiety will be measured by Spielberger's State Trait Anxiety Inventory questionnaire, at three times as three days before colposcopy, 40 minutes before colposcopy and immediately before colposcopy. The main variable is the auriculotherapy that its effect will be evaluated on

anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017043033717N1**

Registration date: **2017-07-25, 1396/05/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-07-25, 1396/05/03

Registrant information

Name

Samaneh Jouya

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2017-05-13, 1396/02/23

Expected recruitment end date

2017-11-14, 1396/08/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of auriculotherapy with electrical stimulation and seeds pressure on anxiety before colposcopy

Public title
Ear acupressure effect on anxiety

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria include: Patient's consent to participate in this study; Have minimum level of literacy; Haven't Problems with speech, hearing or mental barrier to communicate with the investigator; Age over 18 years; Not being pregnant or lactating; Do colposcopy for the first time; Lack of addiction to drugs and alcohol, psychological and severe medical disease; Without history of auriculotherapy treatment in the last 6 month; Absence of wound or lesion at the ears; Having vital signs within normal limits; Absence of unusual sensitivity in touch ear; Having Stressful accident in the last 3 months. Exclusion criteria are: Using certain drug; Unwillingness to continue cooperation; creating stressful events during the study; Itching or inflammation and infection and removing seed more than 24h in the intervention group Seeds.

Age
From **18 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 Mashhad Univercity of Medical

Sciences
Street address
Ghoreshi building-Daneshgah street
City
Mashhad
Postal code
9138813944
Approval date
2017-04-12, 1396/01/23
Ethics committee reference number
IR.Mums.Rec.1396.18

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized Anxiety Disorder

Primary outcomes

1

Description

Anxiety

Timepoint

Before intervention: 3day before colposcopy and 40 minut before colposcopy and after intervention:immediately before colposcopy

Method of measurement

Eshpilberger Questionnaire

Secondary outcomes

1

Description

Pain

Timepoint

Immediately after colposcopy

Method of measurement

Pain visual analog scale

2

Description

Estress

Timepoint

In 4 times: 3day before colposcopy, 40 minut before colposcopy, immediately before colposcopy and immediately after colposcopy

Method of measurement

Estress visual analoge scale

3

Description

Attitude to colposcopy

Timepoint

40 minute before cplposcopy

Method of measurement

Question

Intervention groups**1****Description**

Intervention group1: Auriculotherapy with electrical stimulation, After the above acupoints sterilize with 70% alcohol, the researcher, will be applied Transcutaneous auricular stimulation (TAS) at 4 acupoints (Shenmen, Relaxation, Tranquilizer and Endocrine) with the Pointer Excel II and 2Hz frequency, for 30 seconds on each acupoint. The electrical stimulation will conducted in 40 min before colposcopy on the two ears.

Category

Treatment - Other

2**Description**

Intervention group2: Auriculotherapy with seeds, After the above acupoints sterilize with 70% alcohol, the researcher will attach the vaccariae seeds in place by a piece of opaque adhesive patch and fixed on to the 4 acupoint (Shenmen, relaxation, Tranquilizer, endocrine). The subjects will asked to press each point 60 seconds for three times a day (10:00, 16:00, 22:00 respectively), by themselves. The strength should make the local auricle, flushed and ache. The auriculotherapy will conducted in the external ear on the non dominant side, for three days before doing colposcopy until colposcopy day.

Category

Treatment - Other

3**Description**

Control group: Researcher will be attached opaque adhesive patch without seed, at 4 non related points to anxiety (Finger, Shoulder, Tonsil and Stomach) without any compression, three days before colposcopy until colposcopy day.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Quaem Hospital

Full name of responsible person

Efat Koohjani

Street address

Ahmad abad Street

City

Mashhad

2**Recruitment center****Name of recruitment center**

Emam Reza Hopspital

Full name of responsible person

Kazem Shabani

Street address

Ebnesina Street

City

Mashhad

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Ghoreshi bulding- Daneshgah street

City

Mashhad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Samaneh Jouya

Position

Midwifery Master

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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Sharing plan**Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*