Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Email address
jouyas941@mums.ac.ir

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, Tranqulizder, 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
Ebnesina Street

City
Mashhad
Postal code
-
Phone
+98 51 3761 8946
Fax
-
Email
Jouyas941@mums.ac.ir
Web page address
-

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Nahid Golmakani
Position
Midwifery Master-Assistant Professor
Other areas of specialty/work
Street address
Ebnesina Street
City
Mashhad
Postal code
9137913199
Phone
+98 51 3859 1511
Fax
+98 51 1859 7313
Email
Golmakanin@mums.ac.ir
Web page address
-

Person responsible for updating data

Contact
Name of organization / entity
Mashhad Univercity of Medical Sciences
Full name of responsible person
Samaneh Jouya
Position
Midwifery master student
Other areas of specialty/work
Street address
School of Nursing and Midwifery, Ebne sina street
City
Mashhad
Postal code
-
Phone
+98 51 3761 8946
Fax
-
Email
jouyas941@mums.ac.ir
Web page address
-

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