Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comprasion of the Effect of Auriculotherapy and Mefenamic Acid on Primary Dysmenorrhea Severity and Systemic Symptoms associated with it in students

Protocol summary

Study aim

Determination of effect of ariculotherapy and mefenamic acid on the severity of primary dysmenorrhea and associated with it

Design

Randomized clinical trial with control group

Settings and conduct

This study is a clinical trial study on 90 students of Qom University of Medical Sciences. In recall of students who have criteria for entering the study, they are continuously enrolled in the study. They were recruited by quadruple blocking method in two groups is randomly assigned. A demographic questionnaire and menstrual status are completed first by all samples. Individuals in both groups are initially examined in a basic cycle and are not involved in this intervention cycle, and only all individuals complete the course registration form. Then interventions are performed in two groups in two menstrual cycles, and the form for recording the course information, including menstruation, verbal multi-dimensional scoring system, and pain ruler, is completed.

Participants/Inclusion and exclusion criteria

Single, Iranian, 18-35 years old, Dysmenorrhea with degrees 2- 3 according to verbal multi-dimensional criteria, absence of chronic disease , non-use of pill prevention and weight loss, lack of exercise history,lack of body mass over 30, no smoking, earlessness in ariculotherapy, lack of history of ariculotherapy.

Intervention groups

In auriculotherapy group, intervention is done once a week in 2 cycles of menstruation. At the end of the closing session, the menstrual period is placed seeds at 4 points, and squeezing the seeds 4-6 times a day initially begins the onset of menstrual pain. In the mefenamic acid group, taking the 250 mg capsule first takes 2 capsules for the first menstrual symptom, followed by a capsule every 6 hours, and continues until pain is reduced.

Main outcome variables

Severity of primary dysmenorrhea and general symptoms associated with it

General information

Reason for update

- Due to the prolonged approval and coding process, start and end date recruitment were changed. -The random allocation to each group performed using a four-block size, which explained previously in the section Randomization description. But in protocol abstract, there is a double block, a typographical error that was changed to four-block size. - Overall, for people with different menstrual cycles according to the previously mentioned inclusion criteria (menstrual cycle 24-32 days with menstrual length 3-7 days), auriculotherapy is performed between a minimum of 2-3 and a maximum of 3-4 sessions per cycle. during implementation, we noticed that in the relevant section was corrected.

Acronym

IRCT registration information

IRCT registration number: **IRCT20181207041873N1**
Registration date: **2019-02-24, 1397/12/05**
Registration timing: **prospective**

Last update: **2020-02-06, 1398/11/17**
Update count: **1**

Registration date

2019-02-24, 1397/12/05

Registrant information

Name

Seyedeh Batool Hasanpoor-Azghady

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-01, 1397/12/10
Expected recruitment end date
2019-07-11, 1398/04/20
Actual recruitment start date
2019-03-03, 1397/12/12
Actual recruitment end date
2019-07-15, 1398/04/24
Trial completion date
2019-07-15, 1398/04/24

Scientific title
Comprasion of the Effect of Auriculotherapy and Mefenamic Acid on Primary Dysmenorrhea Severity and Systemic Symptoms associated with it in students

Public title
Effect of Auriculotherapy a on Primary Dysmenorrhea Severity and Systemic Symptoms associated with it
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being single Iranian nationality Age of 35-18 years Having regular menstrual periods (length of 3-7 days and the interval between two menstrual periods 32-32 days) in the last two cycles Having primary dysmenorrhea with rejection of secondary dysmenorrhea with the diagnosis of a specialist Having menstrual pain as a colic or crampy pain in the suprapubic line, sometimes spreading to the lower back and groin that begins with menstruation and lasts for 2-3 days Primary dysmenorrhea with degrees 2 and 3 according to verbal multi-dimensional criteria Experience primary dysmenorrhea in most menstrual cycles External ear on both sides without lumps, swelling, infection or ulcers in the group of Auriculotherapy
Exclusion criteria:
Lack of any known chronic disease and absence of a pacemaker No history of anemia, weakness Non-use of contraceptive pills over the past three months Failure to lose weight during the study Not having a regular exercise activity during the 3 months before the start of the study Lack of body mass index of more than 30 kg per square meter Not having a history of pelvic inflammatory diseases, endometriosis, myoma, and pelvic tumors with the diagnosis of a doctor Non-use of tobacco (cigarettes, hookahs and narcotics) and alcohol No history of any abdominal and pelvic surgery or abnormal ultrasound of the uterus Non-occurrence of severe psychological stress in the last 6 months, such as parental separation, death of first degree relatives and surgical procedures Having no history of mood disorders with expert diagnosis No history of treatment with Auriculotherapy in the last 6 months
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: **90**
Actual sample size reached: **83**
Randomization (investigator's opinion)
Randomized
Randomization description
A researcher at a recall in Qom University of Medical Sciences, after his introduction, explains the sufficient information about the research, including the title of research, the goals of the study, the criteria for entering and leaving the study, the manner and manner of conducting the study for students. Individuals who wish to participate in research with primary dysmenorrhea and inclusion criteria are referred to the researcher by telephone for their research, and are included in the continuous sampling method. The research units are then assigned to the two groups of Auricolotherapy and Mefenamic acid by randomization. In a block random method, quadrilateral blocks are created, in which randomly, half of each block is placed in one group and the other half in the other group. In this study, we want to identify 90 people in two groups of 45 patients with Auricolotherapy and Mefenamic acid, first we identify all four-state states in which half of the people are assigned in the Auricolotherapy group and the other half in the Mefenamic acid group. Then, to each of these four-state combinations that include six modes, we assign one of the digits 1-6. Then we select 25 randomly random numbers from 1 to 6, and we write the combinations of it in succession, and the subjects enter into two groups.
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 Committees of Iran University of Medical Sciences
Street address
Tehran, Hemat Highway next to Milad Tower, Iran

University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-09-29, 1397/07/07

Ethics committee reference number

IR.IUMS.REC.1397.550

Health conditions studied

1

Description of health condition studied

Primary Dysmenorrhea and Systemic Symptoms associated with it

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of primary dysmenorrhea

Timepoint

Measurement in three cycles of menstruation including basal cycle, first and second cycle of menstruation in intervention

Method of measurement

Visual Analogue Scale

2

Description

General symptoms associated with dysmenorrhea

Timepoint

Measurement in three cycles of menstruation including basal cycle, first and second cycle of menstruation in intervention

Method of measurement

Verbal Multidimensional Scoring system

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the auriculotherapy group, it was explained to each person that auriculotherapy is started once every 6 days for 2 cycles of menstruation for each person, and the intervention begins at the end of a menstrual period and continues until the end of the menstrual period. . Totally, for women with different menstrual cycles, the ariculotherapy was performed from at least 2-3 to a maximum of 3 to 4 sessions per cycle each intervention cycle. This practice was carried out by a trained researcher with a degree in auriculotherapy, in a private environment that was designed for this purpose. At the last session of near-menstrual at 4 drops, both ears of herbs were inserted into the ear and explained to people that initiating the onset of the syndrome initially began the onset of menstrual pain, and each point for 1 minute 6 to 4 times a day Press at intervals of at least 1 hour and continue pressing the dots until the end of the menstrual period, and then remove the acne from the pain for 24 hours after relieving pain. Seed in place could stay for 7 days. To avoid forgetting, squeezing the syndas was reminded by telephone and through the virtual group. The strength of the seizures should be such as to cause pain and burning in the outer ear. They were also informed that various feelings might be felt by the pressure of the blood vessels, such as numbness, swelling, mild pain, or heat. People were told that the cheeks were not easily removed and their adhesives relative to body oil They do not react and can not be easily removed from the ear. In the case of going to the bath, the ears should only be washed with water, and until the drying of the ears, do not touch the syringes and inform the researcher if Seyed is detached. To remove the worms, it is best for the patient to put his ears down (ground) The 11 points used to relieve dysmenorrhea were used: the main points of my gravel, thalamic, ziro point and endocrine point, and the anatomical points of the uterus, genitals, ovaries, and the supporting regions of the kidneys, pelvis, vagus, and The prostaglandin is the point. Electric stimulation of the ear after ear disinfection with 70% alcohol and 1 minute of general massage of the ear for relaxation, through the skin at points with a 2-point pointer machine, with a frequency of 2 Hz and a current of 4-2 mA for 20 seconds. Each point was applied by the researcher. At the end of the closing session, the next menstrual period was placed at 4 points in my gravel, thalamic, uterus, and pelvic seated.

Category

Treatment - Other

2

Description

Control group: In the mefenamic acid group, people were told to use a 250 mg mefenamic acid capsule during the two menstrual cycles to make the Amin Pharmaceuticals company with the first symptom of menstrual start, such as cramp, pain or bleeding. How to use it was that the first time 2 capsules and then every 6 hours to take a capsule and continue until pain relief. The study units were told to follow this intervention for both menstruation cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
دانشگاه علوم پزشکی قم

Full name of responsible person
معصومه واحدی

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Shahid Lavasani St. (Coastal) - Qom University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Iran University of Medical Sciences

Proportion provided by this source
50

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
Iran University of Medical Sciences

Full name of responsible person
Masoomeh Vahedi

Position
Student

Latest degree
Master

Other areas of specialty/work
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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

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

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Only part of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Data for researchers and people who are engaged in treatment can apply for them

Under which criteria data/document could be used

Data for researchers and people who are engaged in treatment can apply for them

From where data/document is obtainable

by Email m.vahedi_89@yahoo.com

What processes are involved for a request to access data/document

by Email m.vahedi_89@yahoo.com

Comments

6 months after publishing the results