

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

The effect of Transcutaneous Electrical Acupoint stimulation on women menstrual migraine.

Protocol summary

Study aim

The effect of Transcutaneous Electrical Acupoint stimulation on menstrual migraine.

Design

.This experimental study is a pre- and post-control. The sample size is 60. Convenience sampling will be done. In order to prevent bias, in this study, simple randomization will be used to perform random allocation and then will be randomly divided into one intervention group and two control groups.

Settings and conduct

Patients are referred to psychiatrists and midwives in clinics in Kermanshah. Sampling is done at Sleep Disorders Research Center of Kermanshah University of Medical Sciences, Farabi Hospital. Intervention for each individual for 6 sessions at least 3 days before menstruation, during menstruation and after menstruation for two consecutive cycles in each session. , 5 minutes Acupuncture points are performed for 50 seconds by a student under the supervision of an acupuncturist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) having migraine headache during menstrual phase Exclusion criteria: 1) painkillers and hormone medication during menstruation.

Intervention groups

Individuals are randomly divided into three groups. The intervention group consisted of 20 patients and two control groups of 40 persons. Intervention According to the results of Ahwaz migraine headache questionnaire, the headache status of the patients is determined before the intervention. In the acupuncture treatment group for acupuncture skin acupuncture in the six points, HT7 Shen I in the hands, Sanjiano SP6 in the medial ankle, and L14 Hugo in the thumb and forearm. But in the first control group the same acupuncture points without electrical stimulation are performed by simply touching the pen and in the second control group the acupuncture is performed by the device on non acupuncture points.

Main outcome variables

Menstrual Migraine Headache.

General information

Reason for update

Acronym

TEAS

IRCT registration information

IRCT registration number: **IRCT20191016045129N1**

Registration date: **2020-01-04, 1398/10/14**

Registration timing: **retrospective**

Last update: **2020-01-04, 1398/10/14**

Update count: **0**

Registration date

2020-01-04, 1398/10/14

Registrant information

Name

Faezeh Malekshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3835 2689

Email address

malkshahi2000@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Transcutaneous Electrical Acupoint stimulation on women menstrual migraine.

Public title
The effect of acupuncture on menstrual migraine

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Having a migraine headache in the menstrual phase
Willingness to participate in the study
Exclusion criteria:
Having a physical illness Use of painkillers and hormones during menstruation

Age
From **15 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to prevent bias, in this study, simple randomization method will be used to perform random allocation. By making 60 cards that are matched in appearance, there are 20 cards on the 1 that indicate the intervention group, 20 on the other two, 2 on the first control group and 20 on the other 20. We describe the second control group. Each eligible person then randomly picks up one of these cards on which the code is written, which determines how patients will be randomly assigned to each group.

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 Kermanshah University of

Medical Sciences
Street address
No. 7, Alley chaghakaboudi , Shahid Sq, Elahie Street
City
kermanshah
Province
Kermanshah
Postal code
6719946178
Approval date
2019-09-17, 1398/06/26
Ethics committee reference number
IR.KUMS.REC.1398.690

Health conditions studied

1

Description of health condition studied

Menstrual migraine

ICD-10 code

G43.82

ICD-10 code description

Menstrual migraine, not intractable

Primary outcomes

1

Description

Severity or extent of menstrual migraine

Timepoint

Before and after the intervention

Method of measurement

Ahwaz Migraine Headache Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group at least 3 days before menstruation, during menstruation and after menstruation for two consecutive cycles during six sessions, the student performed acupuncture dermal acupuncture.

Category

Rehabilitation

2

Description

Control group:In the first control group, at least 3 days before menstruation, during menstruation and after menstruation for two consecutive cycles during six sessions, the acupuncture points are touched only by the device without the stimulator.

Category

Rehabilitation

3

Description

Control group: In the second control group, at least 3 days before menstruation, during menstruation and after menstruation for two consecutive cycles during six sessions, the student performed electrical stimulation of the shunt at non-acupuncture points.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi Hospital, Sleep Disorders Clinic

Full name of responsible person

Faezeh malekshahi

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No. 7, Alley Chaghakaboudi , Shahed Square, Elahieh Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Kermanshah 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

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Faezeh Malekshahi

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Province

Kermanshah

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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