Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evaluation clinical effectiveness of the TENS device in reducing menstrual pain

Protocol summary

Study aim
Investigation of the clinical effectiveness of the tennis device in reducing menstrual pain

Design
Clinical trial with a control group, double-blind, randomized, phase 4 on 74 patients.

Settings and conduct
musculoskeletal research center, Isfahan university of medical sciences

Participants/Inclusion and exclusion criteria
1- Women 18-45 years old 2- History of pain during at least the last 3 cycles 3- moderate to severe pain (VAS ≤ 5) that is needed to take painkillers to relieve the pain.

Intervention groups
Experimental group: Arnica tennis device manufactured by Avin Teb Isfahan Medical Engineering Company will be used for intervention. The intervention of one session will be done on the day of menstruation when the participant has the most pain. The pulse width and frequency of the output current are equal to 100 microseconds and 100 Hz, respectively. The size of the electrode area is 45 mm. The time to use the device will be 30 minutes. Participants lie on their side. If you feel pain in the lower abdomen, the self-adhesive electrode will be attached below the level of the navel on the clean and dry skin of the abdomen, and if you feel pain in the lower back, the electrode will be attached to the clean and dry skin of the lower back. To use the skin device, first the electrodes are attached to the skin and after making sure that the device is off, it is connected to the device by means of a connecting wire. Then the device is turned on and the intensity of the current increases to below the pain threshold. After the end of the usage time, the device is turned off and the electrodes are separated from the skin. control group: For the control (placebo) group, all the steps are the same as the test group, but a device that has no output is used.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230814059144N1**
Registration date: **2023-08-20, 1402/05/29**
Registration timing: **prospective**

Last update: **2023-08-20, 1402/05/29**
Update count: **0**

Registration date
2023-08-20, 1402/05/29

Registrant information

Name
Ashraf Mahmoudzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3792 5229

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amahmoudzadeh58@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-26, 1402/06/04

Expected recruitment end date
2023-10-26, 1402/08/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation clinical effectiveness of the TENS device in reducing menstrual pain

Public title
effect of TENS on menstrual pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women 18-45 years old History of pain during at least the last 3 cycles moderate to severe pain (VAS ≤ 5) that was needed to take painkillers to relieve the pain.
Exclusion criteria:
History of lower abdominal surgery Scars, wounds, abdominal skin sensitivity Suffering from cancer, diabetes, heart, immunity, epilepsy and psychological diseases Suffering from other women's diseases such as poly-cystic ovaries, endometriosis and uterine fibroid Using a pacemaker
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
4
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
According to the number of participants in the study plus 20%, code 1 and 2 will be considered. Code 1 will be for the control group and code 2 will be for the test group. Then the codes are written on small pieces of paper and the paper is folded. The folded papers are put into a container and one is randomly picked.
Blinding (investigator's opinion)
Double blinded
Blinding description
The inclusion and exclusion criteria of the study are evaluated by a physiotherapist unaware of the research method and based on clinical tests. Since the names of the groups are written as codes 1 and 2 and the device is used as a placebo (no output) for the control group, the patients are blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Isfahan university of medical sciences
Street address
Isfahan University of Medical Sciences,Isfahan
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.ARI.MUI.REC.1402.092

Health conditions studied

1

Description of health condition studied
menstrual pain
ICD-10 code
N94
ICD-10 code description
Pain and other conditions associated with female genital organs and menstrual cycle

Primary outcomes

1

Description
pain
Timepoint
before, immediately, one hour and 24 hours after the intervention
Method of measurement
visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention of one session will be done on the day of menstruation when the participant has the most pain. The pulse width and frequency of the output current are equal to 100 microseconds and 100 Hz, respectively. The size of the electrode area is 45 mm. The time to use the device will be 30 minutes. Participants lie on their side. If you feel pain in the lower abdomen, the self-adhesive electrode will be attached below the level of the navel on the clean and dry skin of the abdomen, and if you feel pain in the lower back, the electrode will be attached to

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Category
Rehabilitation

2

Description
Control group: The procedure will be similar to the experimental group, but the device has no output

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physiotherapy Clinic, Faculty of Rehabilitation Sciences

Full name of responsible person
Farnaz Jokar

Street address
Isfahan University of Medical Sciences,Isfahan,Iran

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Web page address
https://rehab.mui.ac.ir/fa/clinic/%DA%A9%D9%84%DB%8C%D9%86%DB%8C%DA%A9-%D9%81%DB%8C%D8%B2%DB%8C%D9%88%D8%AA%D8%B1%D8%A7%D9%BE%DB%8C

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Medical Equipment Avin Teb

Full name of responsible person
Mehrdad Sheikhan

Street address
3rd Floor, Unit 13 of Parsian Commercial, Between Aburihan and Falaturi Office Complex, Eshraq North Street, Isfahan

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Isfahan

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Isfehan

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8193914902

Phone
+98 31 3459 7621

Fax
+98 31 3459 7622

Email
info@avintebco.com

Web page address
https://avintebco.com/

Grant name

Grant code / Reference number

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

Title of funding source
Medical Equipment Avin Teb

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ashraf Mahmoudzadeh

Position
Faculty commitments

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Nika Building, Azadegan Alley, Khosropur St, Hazar Jarib St, Isfahan

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The present study is carried out to confirm the effectiveness of the TENS device at the request of the industry, and its results will be reported to Avin Teb Medical Engineering Company in order to obtain the necessary license for mass production.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available