Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Primary Dysmenorrhea in Adolescent girls

Protocol summary

Summary

Objectives: Dysmenorrhea is a common problem among female adolescents. The purpose of this study is to examine the effect of high-frequency transcutaneous electrical nerve stimulation (TENS) on primary dysmenorrhea and to compare the placebo effect by in a randomized controlled study. Study Design: Sixty –four female aged between 14-18 years at the first day of their menstruation cycle randomly selected in two groups (TENS or placebo TENS). Participants‘ physical characteristics and menstrual history were recorded. Intensities of menstrual pain are measured by self-reported pain intensity using visual analog scale (VAS) before and just after treatment. Paired t-test and independent t-test were conducted to compare pain intensity between pre-post treatment and two groups (TENS vs. placebo). Results : The decrease of pain intensity after TENS and placebo were examined. And also concurrent use of analgesic was assessed in the both groups. Conclusions: This result supported that using TENS could be effective in pain reduction among adolescents who were suffered by primary dysmenorrhea.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012072810426N1**
Registration date: **2015-01-21, 1393/11/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-21, 1393/11/01

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medicine and Health Sciences

Expected recruitment start date

2010-01-01, 1388/10/11

Expected recruitment end date

2012-10-01, 1391/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Primary Dysmenorrhea in Adolescent girls

Public title

Effect of Transcutaneous Electrical Nerve Stimulation (TENS) on Primary Dysmenorrhea in Adolescent girls

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criterion: having primary dysmenorrhea.
Exclusion criteria: secondary dysmenorrhea or having any plvic mass or abnormal vaginal bleeding.

Age

From **14 years** old to **18 years** old

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Hamadan university of Medicine and Health Sciences
Street address
Shahid Fahmideh Street- Counterpoint of Mardom Park- Hamadan university of Medicine and Health Sciences
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Postal code
65178
Approval date
2010-08-20, 1389/05/29
Ethics committee reference number
3/1163 /16 /پ

Health conditions studied

1

Description of health condition studied
Primary Dysmenorrhea
ICD-10 code
N.94.4
ICD-10 code description
Primary dysmenorrhoea

Primary outcomes

1

Description
Change in pain intencity
Timepoint
After treatment in the two groups
Method of measurement
VAS

Secondary outcomes

1

Description
Reduce in use of pain killer
Timepoint
Two days after treatment
Method of measurement
Check list

Intervention groups

1

Description
In the active group a TENS device (ENRAF NONIUS Model, four electrodes) with a frequency of 0- 100 and 90-100 pulse /seconds was applied (20 minutes each) respectively, to increase circulation (0-100 pulse/seconds) and to have sedation at the first day of menstrual complaints without taking any analgesics. Patients lied in prone position and a thin pillow placed under their abdomen. Two electrodes were placed to the proximal margin of low back area, and two others were placed to the proximal of gluteal region laterally . The intensity of stimulation was increased up to the tolerated level without leading any contraction .
Category
Treatment - Devices

2

Description
The placebo TENS device had exactly the same appearance as the active TENS, but the placebo TENS had no stimulating output. It was applied for a total of 20 minutes in the prone position to the same regions. Same person provided both active and placebo TENS applications.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hamadan University of Medicine and Health Sciences
Full name of responsible person
Dr. Parisa Parsa
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Sponsors / Funding sources

1

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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
Hamadan University of Medicine and Health 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

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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