

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name

Parisa Parsa

Name of organization / entity

Hamadan University of Medical Sciences

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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

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Shahid Fahmideh Street- Counterpoint of Mardom
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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 intensity

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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Research Center for Chronic Diseases Home Care .
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Saeed Bashirian

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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

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Parisa Parsa

Position

Assistant Professor

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Contact

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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