

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

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parsa@umsha.ac.ir

##### 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

**City**

Hamadan

**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 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

**Street address**

Research Center for Chronic Diseases Home Care .  
Department of Mother and Child Health, Hamadan  
University of Medicine and Health Sciences,  
Hamadan, Iran

City  
Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hamadan University of Medicine and Health Sciences

**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

**Other areas of specialty/work**

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## Person responsible for scientific

## 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*