

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effectiveness using of TENS (Transcutaneous Electrical Nerve Stimulation) in pain controlling while change dressing in hospitalized burned patients

Protocol summary

Summary

Aim: This study was to investigate the influence of TENS (Transcutaneous Electrical Nerve Stimulation) in pain controlling while change dressing in hospitalized burned patients. **Inclusion criteria** All of patients that have 70-15 age old years with grade 2 of burn in hands and legs. **Materials and Methods:** This is a clinical trial study that 60 hospitalized burned patients to burn part in Sabzevar Vasee hospital in 1393. The patients divided simply randomize to three group control (20 peoples), case (20 peoples) and placebo (20 peoples). To third bedridden, takes morphine in group control, TENS with morphine in case group and placebo TENS with morphine in placebo group before beginning change dressing and then changed dresses. Finally after change dressing assessed intensity of patient's pain according to, pain numeric scale 0-10.

General information

Acronym

TENS(Transcutaneous Electrical Nerve Stimulation)

IRCT registration information

IRCT registration number: **IRCT2014101719561N1**

Registration date: **2015-03-17, 1393/12/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-03-17, 1393/12/26

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Sabzevar univercity of medical science

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2014-10-22, 1393/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness using of TENS (Transcutaneous Electrical Nerve Stimulation) in pain controlling while change dressing in hospitalized burned patients

Public title

Effectiveness using of TENS (Transcutaneous Electrical Nerve Stimulation) in pain controlling while change dressing in hospitalized burned patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: All of patients with Superficial and deep by grade 2 of burn; The consciousness burned patients to 4-20 range percent; The patients that have 15-70 age old; The burned patients in upper or lower or upper and lower members. **Exclusion criteria:** The mental

retardation patients that don't talk measure of numeric pain scale; The burned patients less of 4 and more of 20 percent; The pregnant patients (special in third of pregnancy); The patients with heart disorders or have a pace maker; The patients with sensibility to gel; The patients that have an epilepsy.

Age

From **15 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sabzevar University of Medical Science

Street address

Tehran road-side the road police-Sabzevar University of Medical Science

City

Sabzevar

Postal code

9613846776

Approval date

2014-05-12, 1393/02/22

Ethics committee reference number

medsab.Rec.93.4

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T30.2

ICD-10 code description

Burn of second degree, body region unspecified

Primary outcomes

1

Description

pain

Timepoint

while intervention(in third days of hospitalization)

Method of measurement

measure of numeric pain scale

Secondary outcomes

1

Description

skin sensivity to TENS

Timepoint

after of end intervention

Method of measurement

observation

Intervention groups

1

Description

Control Group: Before washing the patient's lesions and exchanging the bandage, 5 mg of Morphine ampoule is infusion and we start to exchange the bandage 15 minutes later and at the last, the Patient's pain level is asked and recorded from the patient on the base of 0-10 pain numerical scale.

Category

Treatment - Drugs

2

Description

Intervention Group: Before washing the patient's wounds and exchanging the dress, infusion Morphine ampoule for 5 mg and we start to exchange the bandage 15 minutes later. Morphine ampoule was infusion before exchanging the dress and then, leads of TENS device were connected to Distal of burned organ and later, we turn on the device and 60-100 HZ frequency rate and 10-30 mA amperage are given and then, we begin to washing and exchanging the bandage and again the patient's pain level during the dress exchange is asked and recorded at the end.

Category

Treatment - Devices

3

Description

Placebo Group: Before washing the patient's wounds and exchanging the dress, 5 mg of Morphine ampoule is infusion and we start to exchange the dress 15 minutes later. Morphine ampoule was infusion before exchange the dress and then, leads of Tens device were connected to Distal of burned organ and later, we turn on the TENS

device but no frequency is given and then, we begin to washing and exchanging the dress and again the patient's pain level during the dress exchange is asked and recorded at the end.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

part burn of sabzevar hospital Vasee

Full name of responsible person

Mohammad Siavoshi

Street address

Vasee hospital

City

Sabzevar

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Mosareza Tadayonfar

Street address

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Sabzevar

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar University of Medical 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**

Sabzevar University of Medical Science

Full name of responsible person

Dr. Mahtab Khajeh

Position

General Surgeon/Responsible of Sabzevar part burn

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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