Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Assessment of The Transcutaneus Electrical Nerve Stimulation Effect on Postoperative Abdominal Pain Intensity in Low Consciousness Patients hospitalized in Intensive Care Unit of Besat Hospital, Hamedan 2015

Protocol summary

Summary

This is an intersecting clinical trial study which investigate the effect of Tens on pain in loss of consciousness patient hospitalized in ICU who were under abdominal surgery(Appendectomy, Cholecystectomy, Herniorrhaphy, Pancreatitis,Lapara Toomey). Inclusion criteria includes patient in the age of 18-65, with not any severe damage, the ability to move at least one upper limb, Loss of consciousness and exclusion criteria includes changes in the patient's level of consciousness to higher or lower level than the inclusion criteria and transfer the patient to another hospital sector. The sample were 35 patient that each of them was once under the influence of placebo TENS and once under the influence of active TENS and then the pain was evaluated after and before each intervention by non-verbal assessment criteria evaluating pain method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062227736N2**
Registration date: **2016-08-25, 1395/06/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-25, 1395/06/04

Registrant information

Name

shahin heidari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 5351

Email address

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2016-02-29, 1394/12/10

Expected recruitment end date

2016-07-10, 1395/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of The Transcutaneus Electrical Nerve Stimulation Effect on Postoperative Abdominal Pain Intensity in Low Consciousness Patients hospitalized in Intensive Care Unit of Besat Hospital, Hamedan 2015

Public title

Assessment of The Transcutaneus Electrical Nerve Stimulation Effect on Pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patient in the age of 18-65, with not any severe damage, the ability to move at least one upper limb, Loss of consciousness with the absence or presence of endotracheal tube. Exclusion criteria: Changes in the patient's level of consciousness to higher or lower level than the inclusion criteria, transfer the patient to another hospital sector.

Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **35**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Rafsanjan University of Medical Sciences
Street address
Imam Ali Blvd, Rafsanjan University of Medical Sciences
City
Rafsanjan
Postal code
Approval date
2016-03-02, 1394/12/12
Ethics committee reference number
IR.RUMS.REC.1394.186

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
Z03.8
ICD-10 code description
Observation for other suspected diseases and conditions

Primary outcomes

1

Description
Pain
Timepoint
Before and Six Hours After TENS
Method of measurement
Behavioral Pain Scale (BPS)

Secondary outcomes

empty

Intervention groups

1

Description
Each patient was under influence of placebo TENS for once in which electrodes were attached on either side of the abdomen surgical suture for 2 hours,but the device was of and there is no electrical stimulation with measuring pain befor and 6 hours after TENS by using behaviorial scale assessment(There is only one group of 35 individuals).
Category
Treatment - Other

2

Description
Each patient was under influence of active TENS for once in which conventional tens with 80 Htz wavelength and 320 mlsecond, a method which is a subset of High TENS, and by the method of regional electrodeing with adhesive electrodes on either side of the abdomen surgical suture with measuring pain befor and 6 hours after TENS by answering the pain intensity scale by researcher(There is only one group of 35 individuals).
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
General ICU, Besat Hospital, Hamedan-
Full name of responsible person
Dr.Rahimi - Miss Jalalmanesh
Street address
Highly specialized besat Hospital, Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Dr.Heidari(PHD)
Street address

Rafsanjan School of Nursing

City

Rafsanjan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan School of Nursing

Full name of responsible person

Jalalmanesh Maryam

Position

Critical Care Nursing Graduate Student

Other areas of specialty/work

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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