Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity

Country

Iran (Islamic Republic of)

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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

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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