

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of transcutaneous electrical nerve stimulation in acupuncture points with the incision site on post operative complications and physiological indicators after appendectomy

Protocol summary

Summary

Objectives: The purpose of this study is to compare the effect of transcutaneous electrical nerve stimulation (TENS) in acupuncture point (SP6, ST36, LI4) with the incision site on post operative complication such as pain, nausea and vomiting and physiological indications.

Inclusion criteria: Men and women between ages 15-45 under appendectomy operation in torbat jaam sajadie hospital after taking cognitive satisfaction are examined.

Exclusion criteria are: history of skin disease, history of cardiac disease, addiction, diabetes, history of cognitive or mental disease, pregnancy and history of using acupuncture or TENS and by accessing any accidental during intervention such as bleeding or withdrawal of participation in intervention will be leaved.

Setting and conduct: Patients will divided accidentally to 4 groups after recovery: first group TENS in acupuncture points, second group TENS in place of incision, third group TENS in form placebo, the forth group researcher does not interfere. In all groups routine cures done during study.

Main outcome measures: pain, nausea and vomiting, physiological indications, amount of taking lenitive before, immediately after intervention, 10 minutes after and at the end of 20 minutes are recorded and compared.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2015061322682N2**

Registration date: **2015-11-07, 1394/08/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-07, 1394/08/16

Registrant information

Name

Mahsa Moazzen Ahmadi

Name of organization / entity

Gonabad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 5722 3514

Email address

moazzenm2@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research Gonabad University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of transcutaneous electrical nerve stimulation in acupuncture points with the incision site on post operative complications and physiological indicators after appendectomy

Public title

Comparison of transcutaneous electrical nerve

stimulation in acupuncture points with the incision site

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: men and women 14-45 years old; under appendectomy. Exclusion criteria; history of skin disease; history of cardiac disease; cognitive disease; diabetes disease; addiction; history of using TENS or acupuncture and pregnancy.

Age

From **15 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients will divided accidentally to 4 groups (Table of random numbers)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Gonabad University of Medical Sciences

Street address

Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi, Iran

City

Gonabad

Postal code

9691793718

Approval date

2015-03-11, 1393/12/20

Ethics committee reference number

GMU.REC.1393.134

Health conditions studied

1

Description of health condition studied

Appendicitis

ICD-10 code

k35-2,k35-

ICD-10 code description

Appendicitis (acute) with generalized (diffuse) peritonitis following rupture or perforation, Acute appendicitis with localized peritonitis with or without rupture or perforation
Acute appendicitis with peritoneal absces,Acute appendicitis without

Primary outcomes

1

Description

pain

Timepoint

before intervention, immediately after intervention, 10 minute after and at the end of 20 minute intervention

Method of measurement

Visual Analogue Scale of pain

2

Description

nausea

Timepoint

before intervention, immediately after intervention, 10 minute after and at the end of 20 minute intervention

Method of measurement

Visual Analogue Scale of nausea

Secondary outcomes

1

Description

amount of pain relief

Timepoint

before intervention, immediately after intervention, 10 minute after and at the end of 20 minute intervention

Method of measurement

cc

2

Description

blood pressure

Timepoint

before intervention,immediately after intervention,10 minute after and at the end of 20 minute intervention

Method of measurement

pressure indicator

3

Description

Heart rate

Timepoint

before intervention, immediately after intervention, 10

minute after and at the end of 20 minute intervention

Method of measurement

Probe monitor

4

Description

respiratory rate

Timepoint

before intervention, immediately after intervention, 10 minute after and at the end of 20 minute intervention

Method of measurement

see chest

Intervention groups

1

Description

15 minute after discharging of recovery in first group, in addition to routine cure in part, patients are cured under transcutaneous electrical nerve stimulation in acupuncture point (LI4, ST36, PC6) put in form of two sided with frequency 100 HZ and circuiting within tolerance for 20 minutes.

Category

Treatment - Other

2

Description

15 minutes after discharging of recovery in second group, in addition to routine cures in part, patients are cured under transcutaneous electrical nerve stimulation in places of incision (4 cm far from cutting place in form two sided) with frequency 100 HZ and circuitry within tolerance for 20 minute.

Category

Treatment - Other

3

Description

15 minute after discharging of recovery, in third group in addition to routine cures in part, patients are cured under transcutaneous electrical nerve stimulation in acupuncture points and incision site (instruments pads are putting in related points but TENS device does not tern) for 20 minute.

Category

Treatment - Other

4

Description

15 minute after discharging of recovery in fourth group, just routine cures are done and there is no intervention by researcher.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sajadie Hospital of torbat jam

Full name of responsible person

Mahsa Moazzen Ahmadi

Street address

Sajadie Hospital, Fariman special road, Torbat Jam, Khorasan Razavi, Iran

City

Torbat jaam

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vic Chancellor for research of Gonabad University of Medical Sciences

Full name of responsible person

Dr Ali Mohammadpour

Street address

Vice chancellor research of Gonabad University of Medical Sciences, Gonabad, Khorasan Razavi, Iran

City

Gonabad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vic Chancellor for research of Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Dr Mousa Sajjadi

Position

PHD of nursing

Other areas of specialty/work

Street address

Gonabad University of Medical Sciences, Gonabad,

Khorasan Razavi, Iran

City

Gonabad

Postal code

9691793718

Phone

+98 51 5722 3513

Fax

+98 51 5722 3815

Email

Sajjadi1975@gmail.com

Web page address

www.gum.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mahsa Moazzen Ahmadi

Position

MSc Student, Department of Medical Surgical Nursing

Other areas of specialty/work

Street address

Sajadie Hospital, Fariman special road, Torbat Jam,
Khorasan Razavi, Iran

City

Torbat Jam

Postal code

9576175544

Phone

+98 51 5252 9312

Fax

+98 51 5252 1817

Email

Moazzenm2@mums.ac.ir

Web page address

www.mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Mahsa Moazzen Ahmadi

Position

MSc Student, Department of Medical Surgical Nursing

Other areas of specialty/work

Street address

Sajadie Hospital, Friman special road, Torbat Jam,
Khorasan Razavi, Iran

City

Torbat Jam

Postal code

9576175544

Phone

+98 51 5252 9312

Fax

+98 51 5252 1817

Email

moazzenm2@mums.ac.ir

Web page address

www.mums.ac.ir

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