

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The comparison of the effect of trans-cutaneous electrical nerve stimulation (TENS) upon sympathetic ganglion and acupuncture points on local circulation of lower extremity in healthy subjects

Protocol summary

Summary

Objective: The comparison of the effect of trans-cutaneous electrical nerve stimulation (TENS) upon sympathetic ganglion and acupuncture points on local circulation of lower extremity in healthy subjects. Design: This is a clinical trial. Sampling method is simple sampling. subjects will be randomly divide to three groups. Setting and Conduct: The blood circulation in the thumb of the left foot will be recorded by laser Doppler flow-meter. Circulation at time zero will be recorded as baseline and then once every 3 minutes to 21 minutes will be measured and compared with the baseline blood flow. Participants: 75 healthy volunteers (male and female) aged 18 to 25 years. Intervention: Group1 will receive low frequency electrical stimulation in the thoracic-lumbar sympathetic ganglion (T12,L1,L2). Group2 will receive stimulation in acupuncture points (EX-LF10, SF36) and group3 will receive stimulation in the middle of leg. The electrical stimulation will apply to these areas for 21 minutes. Outcome measures: The blood circulation in the thumb of the left foot.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016022126674N1**
Registration date: **2016-04-04, 1395/01/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-04, 1395/01/16

Registrant information

Name

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Name of organization / entity

Shiraz University of Medical Sciences, School of Rehabilitation Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Shiraz University of Medical Sciences

Expected recruitment start date

2011-09-21, 1390/06/30

Expected recruitment end date

2012-04-19, 1391/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of trans-cutaneous electrical nerve stimulation (TENS) upon sympathetic ganglion and acupuncture points on local circulation of lower extremity in healthy subjects

Public title

The effect of electrical stimulation on the circulation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Healthy subjects Age range of 18 to 25
 Exclusion criteria: Autonomic system disorders
 cardiovascular disease Reynold's disease Cigaret abuse
 Vasodilatory drug use

Age
 From **18 years** old to **25 years** old

Gender
 Both

Phase
 4

Groups that have been masked
No information

Sample size
 Target sample size: **75**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Single blinded

Blinding description

Placebo
 Not used

Assignment
 Parallel

Other design features
 Blocked randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Zand Street

City

Shiraz

Postal code

Approval date

2011-08-03, 1390/05/12

Ethics committee reference number

CT-90-56-37

Health conditions studied

1

Description of health condition studied

Circulation disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

lower etremity circulation

Timepoint

Before intervention, Just after intervention, each 3 minutes till 21 minutes after intervention

Method of measurement

Laser Doppler flowmetry

Secondary outcomes

empty

Intervention groups

1

Description

Trans-cutaneous electrical nerve stimulation on thoracic-lumbar sympathetic ganglion

Category

Other

2

Description

Trans-cutaneous electrical nerve stimulation on acupuncture points

Category

Other

3

Description

Trans-cutaneous electrical nerve stimulation on middle of leg (control)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz university of Medical Sciences, School of Rehabilitation Sciences

Full name of responsible person

Saeed Heidari

Street address

Abiverdi1 Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shiraz University of

Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

Street address

Zand Street, Vice Chancellor for research of Shiraz
University of Medical Sciences

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Shiraz

Grant name

Grant code / Reference number

CT-90-56-37

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

Yes

Title of funding source

Vice chancellor for research, Shiraz 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

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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