Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

investigation of the effect of propranolol on sympathetic skin response and bone mass density of burn patients

Protocol summary

Summary

Charts of 200 registered patients with electrical burns in Shiraz burn center will be reviewed. We will includ 18 to 50 years old patients experiencing electrical injury 15 days to 3 months prior to the study. Those patients who don’t have the exclusion criteria will fill in the informed consent form. Bone mineral density (BMD), T scores, and Z scores at lumbar vertebrae and left femur of the participants will be measured . Sympathetic skin response (SSR) of the subjects will also be recorded from both soles and both palms. Then the patients will be divided into two groups using block randomization. And the case group will recieve 80 mg propranolol / d ay for 12 weeks and then gradually tapered to discontinue in 1 week. And the control group will receive placebo for the same duration. SSR recording and BMD measurement will be repeated for both groups the day after the last dose and 9 months later With the methods described for these measurements at the beginning of the study. The gathered data will be analyzed statistically using SPSS 16.0. Independent sample t-test will be used for comparing means between the two groups. And the correlation between quantitative variables will be tested with Pearson correlation coefficient. $P < 0.05$ will be considered statistically significan

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111930974N1**
Registration date: **2017-01-18, 1395/10/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name
Zohreh Eshghi
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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eshghi_z@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigation of the effect of propranolol on sympathetic skin response and bone mass density of burn patients

Public title

investigation of the effect of propranolol on sympathetic skin response and bone mass density of burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

We will include 18 to 50 years old patients experiencing electrical injury 15 days to 3 months prior to the study. Exclusion criteria are as follows: positive history of joint or bone disease; neuropathy (central or peripheral);

diabetes mellitus or consumption of any drug affecting the autonomic nervous system; any cast; skin lesion, skin graft, or scar at the sites of SSR recording or stimulus (palms, soles, wrists, or ankles) that make technical problems for SSR recording; contraindications of propranolol administration such as bronchial asthma, pronounced bradycardia, manifest heart failure, second and third degree heart block, hypersensitivity to propranolol. Any patient with evidence of peripheral neuropathy on 4 limb electrophysiologic study (done at the beginning of the study after filling in the written informed consent).

Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand St.
City
Shiraz
Postal code
Approval date
2016-11-02, 1395/08/12
Ethics committee reference number
IR.SUMS.MED.1395.54

Health conditions studied

1

Description of health condition studied
Burn
ICD-10 code
T20-32
ICD-10 code description
Burns and corrosions

Primary outcomes

1

Description
Bone mass desitometery
Timepoint
Before study and 3 months, 9 months after study
Method of measurement
Bone mass densitometery

2

Description
Sympathetic skin response
Timepoint
Before study and 3 months, 9 months after study
Method of measurement
SSR

Secondary outcomes

1

Description
Decreased blood pressure
Timepoint
Before and every 2 weeks after study
Method of measurement
Mesurment of blood pressure

Intervention groups

1

Description
The control group will receive placebo for 12 weeks
Category
Placebo

2

Description
The intervention group will recieve 80 mg propranolol / day for 12 weeks and then gradually tapered to discontinue in 1 week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Physical Medicine and Rehabilotation Depatment,

Shiraz University of Medical Sciences

Full name of responsible person

Eshghi Zohreh

Street address

Faghihi hosptal

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Ms. Akbarnezhad

Street address

Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Shiraz University of Medical Sciences

Full name of responsible person

Zohreh Eshghi

Position

MD

Other areas of specialty/work

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eshghi_z@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Physical Medicine and Rehabilitation Department, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Sharareh Roshanzamir

Position

MD, assistance professor

Other areas of specialty/work

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Full name of responsible person

Zohre Eshghi

Position

MD

Other areas of specialty/work

Street address

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Postal code

Phone

+98 71 3231 9040

Fax

Email

Web page address

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