

# 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 include 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 receive 80 mg propranolol / day 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 significant.

#### 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 917 781 5296

##### Email address

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 desitometry

**Timepoint**

Before study and 3 months, 9 months after study

**Method of measurement**

Bone mass densitometry

**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 Department,

Shiraz University of Medical Sciences  
**Full name of responsible person**  
Eshghi Zohreh  
**Street address**  
Faghihi hospital  
**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**  
**Street address**  
Physical Medicine and Rehabilitatin Department,  
Faghihi hospital  
**City**  
Shiraz  
**Postal code**  
**Phone**  
+98 71 3231 9040  
**Fax**  
**Email**  
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**  
**Street address**  
Physical Medicine and Rehabilitation Department,  
Faghihi hospital  
**City**  
Shiraz  
**Postal code**  
**Phone**  
+98 71 3231 9040  
**Fax**  
**Email**  
sharareh.roshanzamir@sums.ac.ir  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Zohre Eshghi  
**Position**  
MD  
**Other areas of specialty/work**  
**Street address**  
Physical Medicine and Reahabilitation Depatment,  
Faghihi hospital  
**City**  
Shiraz  
**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*