

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of pentoxifylline in the efficacy, safety, and tolerability of, and treatment satisfaction with, Carbon dioxide laser in patients with burn scars : A blinded randomized controlled trial

#### Protocol summary

##### Study aim

Evaluating oral pentoxifylline in the efficacy, safety, tolerability, treatment satisfaction of Carbon dioxide laser in patients with burn scars

##### Design

Parallel group, randomized, blinded (assessor and analyst), phase 3 RCT on 44 burn scar patient. Randomization by random generation of SPSS software.

##### Settings and conduct

one group underwent three sessions of CO2 laser (DEKA SmartXide 2016, Italy) power 12 Watts; stacking 2; spacing, 800 µm, dwell time 800 µsec, at 45-day intervals and the other group received the same CO2 laser treatment protocol plus pentoxifylline 400 mg twice daily for four months.

##### Participants/Inclusion and exclusion criteria

Patients between 18-50 years of age with burn scars, with the Vancouver Scar Scale of 5-12. Patients with wound infection, associated collagen vascular disorders, or chronic cutaneous diseases, scars were less than six months old or history of previous treatment with corticosteroids, chemo- or radiotherapy were excluded from the study.

##### Intervention groups

one group (control) underwent three sessions of CO2 laser at 45-day intervals and the other group (treatment) received the same CO2 laser treatment protocol plus pentoxifylline 400 mg twice daily for four months.

##### Main outcome variables

Improvement of VSS score  
Tolerability of treatment  
Adverse events  
Patients' satisfaction

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230613058476N1**

Registration date: **2023-07-30, 1402/05/08**

Registration timing: **retrospective**

Last update: **2023-07-30, 1402/05/08**

Update count: **0**

##### Registration date

2023-07-30, 1402/05/08

##### Registrant information

###### Name

Sarah Dilmaghani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 912 123 2647

###### Email address

sarah.dilmaghani@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2021-02-19, 1399/12/01

##### Actual recruitment start date

2020-06-21, 1399/04/01

##### Actual recruitment end date

2020-09-22, 1399/07/01

##### Trial completion date

2021-05-05, 1400/02/15

##### Scientific title

The effect of pentoxifylline in the efficacy, safety, and tolerability of, and treatment satisfaction with, Carbon dioxide laser in patients with burn scars : A blinded

randomized controlled trial

### Public title

Efficacy of pentoxifylline in CO2 laser treatment of burn scars

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients between 18-50 years of age Having burn scars with the Vancouver Scar Scale of 5-12

#### Exclusion criteria:

Evidence of wound infection associated collagen vascular disorders history of other chronic cutaneous diseases scars less than six months old recent treatment with corticosteroids, chemo- or radiotherapy

### Age

From **18 years** old to **50 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Outcome assessor
- Data analyser

### Sample size

Target sample size: **22**

Actual sample size reached: **22**

### Randomization (investigator's opinion)

Randomized

### Randomization description

To randomize the patients in this study, the stratified block randomization method was used by R software. To ensure balance between the two groups, stratification parameters including age and sex were selected. According to the age range of the patients, which was 18-50 years, two subgroups of 18 to 30 years (young) and 30 to 50 years (middle-aged) and for gender, male or female were selected as stratification subgroups, and finally the samples were divided into four strata, young men - middle-aged men - young women - middle-aged women. Then, according to the size of each block, the randomization function was used to assign patients to two groups, group A (Co2 laser + pentoxifylline) or group B (CO2 laser alone).

### Blinding (investigator's opinion)

Double blinded

### Blinding description

The physician evaluating treatment responses was blind to the patient's treatment groups. Also, the data analyzer was blind to the groups. The care giver who provided oral treatment was the only person informed by the subjects grouping. The assessors (selected from blinded dermatology residents) who performed followups and completed questionnaires and data analyst (from outside the research group) were completely blinded on the subjects' allocations.

### Placebo

Not used

### Assignment

Parallel

### Other design features

-

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Iran University of medical sciences

##### Street address

Iran University of medical Sciences, Junction of Shahid Hemmat & Shahid Chamran Expressways, Tehran,

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

#### Approval date

2020-05-23, 1399/03/03

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.375

## Health conditions studied

### 1

#### Description of health condition studied

Burn Scar

#### ICD-10 code

T95

#### ICD-10 code description

Sequelae of burns, corrosions and frostbite

## Primary outcomes

### 1

#### Description

Improvement of burn scar

#### Timepoint

Before treatment, one and two months after the start of the laser sessions, and three months after the completion of therapy.

#### Method of measurement

modified Vancouver Scar Scale (VSS)

### 2

#### Description

Satisfaction of patients

#### Timepoint

Before treatment, one and two months after the start of the laser sessions, and three months after the completion of therapy.

#### Method of measurement

Visual Analogue Scale (1-3)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: CO2 laser + Oral pentoxifylline

#### Category

Treatment - Other

### 2

#### Description

Control group: CO2 laser

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul-e-Akram Hospital

##### Full name of responsible person

Azadeh Goodarzi

##### Street address

Rasoul Akram hospital, W Niayesh St, Sattarkhan Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 1000

##### Email

SchoolOfMedicine@iums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Hazrat Fatemeh (S) Reconstructive and Plastic Surgery Training Center

##### Full name of responsible person

Azadeh Goodarzi

##### Street address

Hazrat Fatemeh (S) Reconstructive and Plastic Surgery Training Center, 21st St, Seyyed Jamaluddin Asadabadi St, Yusuf Abad

##### City

Tehran

##### Province

Tehran

##### Postal code

1433933111

##### Phone

+98 21 8871 7272

##### Email

SchoolOfMedicine@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr Reza Falak

##### Street address

Iran University of medical sciences, Hemat Highway next to Milad Tower

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 8670 1021

##### Email

schoolofmedicine@iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Sarah Dilmaghani

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dermatology

##### Street address

Dermatology Department, Rasoul-e-akram hospital, Niyayesh St ,Sattarkhan Ave,

##### City

Tehran

##### Province

Tehran  
**Postal code**  
14535  
**Phone**  
+98 912 123 2647  
**Fax**  
**Email**  
sarah.dilmaghani@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Sarah Dilmaghani  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Dermatology Department, Rasoul-e-Akram Hospital,  
Niyayesh St ,Sattarkhan St  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1313114456  
**Phone**  
+98 912 123 2647  
**Fax**  
**Email**  
sarah.dilmaghani@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences

**Full name of responsible person**  
Sarah Dilmaghani  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Dermatology  
**Street address**  
Dermatology Department, Rasoul-e-Akram hospital ,  
Niyayesh St, Sattarkhan St  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1313114456  
**Phone**  
+98 21 6435 1000  
**Fax**  
**Email**  
sarah.dilmaghani@yahoo.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable