

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Investigation of the analgesic effects of intravenous laser in burned patients with grade 3 and b2 and higher than 20%

Protocol summary

Study aim

The purpose of this study was to determine the analgesic effects of intravenous laser in patients with grade 3 and b2 burns with a high percentage of 20%.

Design

The design of this study was a randomized clinical trial. Twenty patients with grade 3 and b2 burns with a high incidence of 20% after rendering were divided into two groups of control and treatment. The treatment group in addition to the standard treatment receives the dose of laser therapy and the control group receiving the inert dose laser. -

Settings and conduct

In this study, patients with burns hospitalized at Shahid Motahhari Hospital are randomly divided into two groups of laser and control. A non-physician performs randomization. People who fill in the pain questionnaire and record drug use and a person who is reviewed the results are unaware of laser and control groups.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include patients aged 20-50 years old; patients with grade 3 and b2 burns with a higher than 20% degree; informed consent; exclusion criteria include chronic patients with continuous onset drug use; addicted people; women Pregnant; Cancer patients.

Intervention groups

laser group: are also treated with intravenous laser for 1 week in addition to daily routine therapy. For laser irradiation, red light is used, 655 nm, 10 mW, 10 jules. control group: the laser is irritated with a non-therapeutic dose

Main outcome variables

The pain score of patients in both groups is measured and recorded for three to five days after starting treatment every 3 hours based on the Visual Analog Scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111121008146N16**

Registration date: **2018-01-02, 1396/10/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-02, 1396/10/12**

Update count: **0**

Registration date

2018-01-02, 1396/10/12

Registrant information

Name

Mohammadreza Razaghi

Name of organization / entity

Laser application in medical sciences research center

Country

Iran (Islamic Republic of)

Phone

+98 21 2271 8021

Email address

laser.cntr@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the analgesic effects of intravenous laser in burned patients with grade 3 and b2 and higher than 20%

Public title

The effect of intravenous laser in burned patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients aged 20-50 years patients with grade 3 and b2 burns with a higher than 20% informed consent

Exclusion criteria:

chronic patients with continuous onset drug use addicted people pregnant women Cancer patients

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned with simple and individual randomization into two groups of laser and control with 1: 1 random numbers table. A person other than the physician conducts randomization.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, those who fill in the pain questionnaire, record the drug intake, and examine the results.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST. Yemen street, Shahid Chamran highway, Tehran

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2017-10-29, 1396/08/07

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.515

Health conditions studied

1

Description of health condition studied

burn with grade 3 and b2 and higher than 20%

ICD-10 code

L10-L14

ICD-10 code description

Bullous disorders

Primary outcomes

1

Description

Pain score of patients

Timepoint

Three to five days after starting treatment every 3 hours

Method of measurement

McGill questionnaire scoring system and VAS mark

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the laser group receive routine daily treatment for 1 week with intravenous laser with red light, 655 nm, 10 mW, 10 jules.

Category

Treatment - Other

2

Description

Control group: They are treated with medicine plus non-therapeutic doses of shame laser.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser Application Research Center in Medical

Sciences

Full name of responsible person

Dr.Mohammad Reza Razaghi

Street address

Shohadaye Tajrish Hospital, Tajrish, Tehran

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Province

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laser.cntr@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti
University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi ST.
Yemen street, Shahid Chamran highway, Tehran

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Tehran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahid Beheshti 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

Laser Application Research Center in Medical Science

Full name of responsible person

Dr.Mohammad Reza Razaghi

Position

urologist

Latest degree

Specialist

Other areas of specialty/work

Urology

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Person responsible for updating data

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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

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

Data Dictionary

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