

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Application of Low level Laser Therapy After Split Thickness Skin Graft in Grade 2-3 Burn Ulcers

Protocol summary

Summary

(1) Objectives: Evaluate the efficacy of Low Level laser therapy after Split thickness skin graft in type 2-3 burn ulcers. (2) Design: The study population is patients with type 2 or 3 burn ulcers admitted to Motahari hospital and have at least two symmetric ulcers in their body, one ulcer will include in intervention group and the other will use as control randomly by dropping coin. At least five patients will be recruited and the trial will be conducted as triple blind, phase three, mono centric trial. (3) Setting and conduct: Skin graft surgery will be applied for both ulcers and then laser therapy will be applied for the ulcer which has been randomly selected for intervention group. Ultimately Intervention and control ulcers will be compared regarding ulcer size and side effect of surgery. (4) Participants: Patients with type 2 or 3 burn ulcers without systematic diseases or photosensitization. (5) Intervention: Low level laser therapy after skin graft. (6) Main outcome measures: Wound healing, Hypertrophic scar, rate of wound healing, wound dehiscence

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016020226069N2**

Registration date: **2016-02-15, 1394/11/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-15, 1394/11/26

Registrant information

Name

Fereshteh Ansari

Name of organization / entity

Razi Vaccine and Serum Research Institute

Country

Iran (Islamic Republic of)

Phone

+98 26 3405 0400

Email address

ansarif@ut.ac.ir

Recruitment status

Recruitment complete

Funding source

Laser Application in Medical Sciences Research Center,
Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-02-08, 1394/11/19

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Application of Low level Laser Therapy After Split
Thickness Skin Graft in Grade 2-3 Burn Ulcers

Public title

Application of Low level Laser Therapy After Skin Graft in
Burn Ulcers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with symmetric type 2 or 3
burn ulcers Exclusion criteria: bleeding tendency;
presences of gangrene; renal failure; systemic disease;
pregnancy; epilepsy; photosensitivity

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 5

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Not 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

Shahid Beheshti University of Medical science, Next to Ayatollah Taleghani Hospital ,Evin , Tehran, Iran

City

Tehran

Postal code

198396-3113

Approval date

2015-11-28, 1394/09/07

Ethics committee reference number

IR.SBMU.RAM.REC.13940.363

Health conditions studied**1****Description of health condition studied**

Degree two or three burn ulcer

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Wound size

Timepoint

End of first and second week after treatment

Method of measurement

Pictzar software

Secondary outcomes**1****Description**

Hypertrophic scar

Timepoint

By the end of first, second, third and sixth month after treatment onset

Method of measurement

Vancouver scar scale

2**Description**

Rate of healing

Timepoint

The end of first and second week after treatment onset

Method of measurement

Examination

3**Description**

Wound dehiscence

Timepoint

The end of first and second week after treatment onset

Method of measurement

Examination

Intervention groups**1****Description**

Intervention group: Skin graft and Low level laser therapy

Category

Treatment - Other

2**Description**

Control group: Skin graft

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Motahari Hospital

Full name of responsible person

Noshafarin Kazemikhoo

Street address

hahid Motahari treatment center, Rashid Yasemi street, Valiasr street

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Laser application in medical science research centre

Full name of responsible person

Dr Parvin Mansouri

Street address

Shohada Tajrish Hospital, Laser application in medical sciences research center

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Laser application in medical science research centre

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

Skin and Stem Cell Research Center

Full name of responsible person

Nooshafarin Kazemikhoo

Position

PhD

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Fereshteh Ansari

Position

PhD student of epidemiology

Other areas of specialty/work

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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