

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Investigation of effects of low level laser therapy on prognosis of Split Thickness Skin Graft in Type3 Burn ulcers of Diabetic Patients

Protocol summary

Summary

(1) Objectives: The purpose of study is introducing a new therapeutic method for accelerating healing with better prognosis in diabetic 2 patients with burn ulcers. (2) Design: The study population is Diabetic type 2 patients with grade 3 burn ulcers, candidate for amputation in Motahari hospital. This study will be conducted as unicenter case series without blinding and sample size is 13. This would be a pilot study for phase 3 clinical trial. (3) Setting and conduct: We will use 650 nm red laser light, 2 J/Cm² for the bed of the ulcer and 810 nm infra-red laser light 6 J/Cm² for the margins along with intravenous laser therapy with 660 nm red light, before and after Split Thickness Skin Graft (STSG) for treating grade 3 burn ulcers in diabetic ulcers. (4) Intervention: Low level laser therapy before and after Split Thickness Skin Graft. (5) Participants: Diabetic type 2 patients with grade 3 burn ulcers, candidate for amputation and main exclusion criteria is systematic diseases. (6) Main outcome measures: The primary outcome is frequency of patients needing amputation surgery and secondary outcome is changes in the size of burn ulcer after treatment.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016011726069N1**
Registration date: **2016-02-15, 1394/11/26**
Registration timing: **retrospective**

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)

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+98 26 3405 0400

Email address

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Recruitment status

Recruitment complete

Funding source

Skin and stem cell research center

Expected recruitment start date

2015-12-06, 1394/09/15

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of effects of low level laser therapy on prognosis of Split Thickness Skin Graft in Type3 Burn ulcers of Diabetic Patients

Public title

Investigation of effects of low level laser therapy on success of Split Thickness Skin Graft in Burn ulcers of Diabetic Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with diabetes and grade 3 burn ulcers, according to Wagner classification Exclusion

criteria: were bleeding tendency; presences of gangrene; renal failure; systemic disease; pregnancy; epilepsy; photosensitivity

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 13

Randomization (investigator's opinion)

N/A

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

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

7th Floor , 2nd SBUMS Bldg. ,Next to Ayatollah Taleghani Hospital, Evin , Tehran, Iran. Post code: 198396-3113

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**

Type 3 burn ulcer in diabetic 2 patients

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

Amputation surgery

Timepoint

Before laser therapy, After surgery, After laser therapy, three month after laser therapy

Method of measurement

physician diagnosis

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

Size of type 3 burn ulcer

Timepoint

Before laser therapy, After surgery, After laser therapy, three month after laser therapy

Method of measurement

Pictzar software

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

Intervention group: Low level laser therapy and Split Thickness Skin Graft Intervention in control group: No control group

Category

Treatment - Other

2**Description**

Control group: -

Category

N/A

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

Shahid Motahari treatment center

Full name of responsible person

Nooshafarin Kazemikhoo

Street address

Shahid Motahari treatment center, Rashid Yasemi street, Valiasr street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Skin and Stem Cell
Research Center

Full name of responsible person

Dr Parvin Mansouri

Street address

No;4, Maryam alley, the southern Kamranyeh street.

City

Tehran

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 of Skin and Stem Cell
Research Center

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

Medical Genetics PhD

Other areas of specialty/work**Street address**

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Ph D student of epidemiology

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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