

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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/Cm<sup>2</sup> for the bed of the ulcer and 810 nm infra-red laser light 6 J/Cm<sup>2</sup> 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)

##### Phone

+98 26 3405 0400

##### Email address

ansarif@ut.ac.ir

#### 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**

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

**City**

Tehran

**Postal code**

14155-6453

**Phone**

+98 21 2221 2537

**Fax****Email**

nooshakazemi@gmail.com

**Web page address**

### Person responsible for scientific 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**

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

**City**

Tehran

**Postal code****Phone**

+98 21 2221 2537

**Fax****Email**

nooshakazemi@gmail.com

**Web page address**

### Person responsible for updating data

**Contact****Name of organization / entity**

Skin and Stem Cell Research Center

**Full name of responsible person**

Fereshteh Ansari

**Position**

Ph D student of epidemiology

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

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

**City**

Tehran

**Postal code**

14155-6453

**Phone**

+98 21 2221 2537

**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*