

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Analysis the Effects of Autologous Fibroblast Transplantation and Low-Level Laser Therapy in the Healing Process of Grade 2 Burn wounds in Diabetic patients

Protocol summary

Summary

(1) Objectives: Evaluate the efficacy of Autologous Fibroblast Transplantation along with Low-Level Laser therapy in grade 2 burn ulcers in diabetic patients. (2) Design: The study population is diabetic patients with type 2 burn ulcers that are hospitalized in Shahid Motahari Burn center 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 without blinding, phase three, mono centric trial. (3) Setting and conduct: Laser therapy will be applied for the ulcer which has been randomly selected for intervention group and then fibroblast cells will be sprayed on it. Classic treatment of ulcers will be applied for control group. Ultimately Intervention and control ulcers will be compared regarding time to healing and healing rate. (4) Participants: Diabetic patients with type 2 burn ulcers without systematic diseases or photosensitization. (5) Intervention: Autologous fibroblast transplantation after Low level laser therapy. (6) Main outcome measures: Wound healing, Hypertrophic scar, rate of wound healing

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016050226069N3**
Registration date: **2016-06-21, 1395/04/01**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-21, 1395/04/01

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 science research centre

Expected recruitment start date

2015-03-01, 1393/12/10

Expected recruitment end date

2016-04-22, 1395/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analysis the Effects of Autologous Fibroblast Transplantation and Low-Level Laser Therapy in the Healing Process of Grade 2 Burn wounds in Diabetic patients

Public title

Analysis the Effects of Fibroblast Transplantation and Laser Therapy in the Healing Process of Grade 2 Burn wounds in Diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients with symmetric type 2 burn ulcers
Exclusion criteria: pregnancy; photosensitivity; chronic disease that needs medication; malignancy

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 5

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not 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 Tehran University of Medical Sciences

Street address

Poursina Street, 16th Azar Street, Enghelab Avenue

City

Tehran

Postal code

1417614411

Approval date

2016-01-18, 1394/10/28

Ethics committee reference number

IR.TUMS.REC.1394.1683

Health conditions studied

1

Description of health condition studied

Degree two burn ulcer

ICD-10 code

T20.2, T21

ICD-10 code description

Burn of second degree of head and neck, Burn of second

degree of trunk, Burn of second degree of shoulder and upper limb, except wrist and hand, Burn of second degree of wrist and hand, Burn of second degree of hip and lower limb, except ankle and foot,

Primary outcomes

1

Description

Wound size

Timepoint

Before treatment, Two weeks after laser therapy onset, Two weeks after fibroblast transplantation

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

After two weeks of laser therapy onset, After two weeks of fibroblast transplantation

Method of measurement

Examination

Intervention groups

1

Description

Intervention group: Laser therapy and Autologous Fibroblast Transplantation

Category

Other

2

Description

Control group: Classic treatment of burn ulcer

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Hospital

Full name of responsible person

Noshafarin Kazemikhoo

Street address

Shahid Motahari treatment center, Rashid Yasemi street, Valiasr street Tehran Iran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Skin and stem cell research center

Full name of responsible person

Dr. Mohammad Ali Nilforooshzadeh

Street address

no:4, Maryam Alley, the southern Kamranyeh, Sadr High way

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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

PhD

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

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

City

Tehran

Postal code**Phone**

+98 21 2227 8950

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

PhD

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

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

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

PhD

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

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

City

Tehran

Postal code**Phone****Fax****Email**

ansarif@ut.ac.ir

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