

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Adjunctive effect of light therapy in some criteria on wound healing in burns patient

Protocol summary

Study aim

Determining the adjunctive effect of light therapy in some criteria on wound healing in burns patient

Design

A single-blind study will be conducted on 50 patients. The samples are placed in two intervention and control groups by random block allocation method.

Settings and conduct

The samples are burn patients hospitalized in Imam Musa Kazem (AS) Isfahan, who are placed in two intervention and control groups by random block allocation method. Blinding is done in such a way that the data collectors and wound evaluators will not be aware of the allocation method and the device users will not participate in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-60 years; burn percentage 20% to 40%; burn degree 2 superficial and deep; Burns with hot liquids or hot steam Exclusion criteria: lack of consent and cooperation of patients to participate in the study; history of underlying disease; more than 6 hours from the occurrence of the burn to admission to the hospital; BMI less than 18.5 and more than 30

Intervention groups

Light irradiation will be daily for 6 minutes in 10 sessions, with a distance of 10 cm from the wound (13). If the patient is discharged before the end of light therapy sessions or wound closure, follow-up will be done for the participant's daily visit until the wound is closed and the light therapy sessions are completed. Before each dressing session, the wound will be opened and washed with 0.9% saline wash. Then, the usual treatment protocol for the wound will be implemented. In the control group, the wound will be exposed to open air for 6 minutes.

Main outcome variables

Outcome variables include: The Vancouver Scar scale, serum level of neutrophils, serum level of lymphocytes,

and wound evaluation score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230108057074N1**

Registration date: **2023-03-06, 1401/12/15**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-06, 1401/12/15**

Update count: **0**

Registration date

2023-03-06, 1401/12/15

Registrant information

Name

Ehsaneh Najari ardestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3462 3648

Email address

ehsanehnajari@mail.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adjunctive effect of light therapy in some criteria on wound healing in burns patient

Public title

Adjunctive effect of light therapy in some criteria on wound healing in burns patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patient with 18-60 years total burn surface area 20%-40% burn degree:2 partial thickness and full thickness burn injury with scald

Exclusion criteria:

History of underlying disease, immune system disorders/blood circulation disorders/substance abuse and pregnancy A history of taking blood thinners The interval of more than 6 hours from the occurrence of burns to admission to the hospital Presence of trauma in the wound BMI less than 18.5 and more than 30

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples are divided into intervention and control groups by random block allocation method. The total volume of the sample is divided into smaller groups that can be divided and an integer number is obtained, called blocks, so that inside each block there are four people from The sample volume is placed. Due to the fact that with a sample size of 30 and a block of 4, an integer number is not obtained, so the number 32 is considered. The placement of people (4 people) inside each block is imagined and recorded from the total sample size of the test and control group {(CACA)(CCAA)(ACCA)(ACAC)}. A number is assigned to each of these situations and recorded (CACA=4)(CCAA=3)(ACCA=2)(ACAC=1). The numbers are written on spherical objects of the same size and color and are thrown into the bag, and a person who is not in the work flow is asked to remove the objects from the bag for the required number of blocks, however repeated, and after Registering the number on the item, the item is returned to the bag. In this way, sampling is done according to the order of the blocks and the number taken out of the bag. It is necessary to explain that the previous block must be completed in order to complete the next block.

Blinding (investigator's opinion)

Single blinded

Blinding description

The data gatherer and wound evaluator do not know low to allocate groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences,Isfahan,Iran

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-09-12, 1401/06/21

Ethics committee reference number

IR.ARI.MUI.REC.1401.188

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T20-T32

ICD-10 code description

Burns and corrosions

Primary outcomes

1

Description

Wound healing score

Timepoint

At the admission until the wound is closed, daily

Method of measurement

A photo will be taken of the patient's wound with a standard camera at a distance of 40 cm on a white background with sufficient light, and the evaluation form will be filled out daily for participation. will be completed.Wound healing parameters will be performed according to the standard method described by Monstrey et al., which includes edema of the burned area; type of wound discharge; the amount of wound discharge; type

of necrotic tissue in the wound; amount of necrotic tissue in the wound; The degree of granulation of the wound and the degree of epithelization of the wound. Each parameter will be given a score from 1 to 5 according to the Likert scale. The wound evaluation form will be completed based on the photos taken by two plastic surgery specialists with more than 15 years of experience in the field of burns. A complete patient history without treatment details will be provided to the evaluators. Based on the photos taken of the wound, they will independently answer the questions in the wound evaluation section.

2

Description

Serum level of white blood cells

Timepoint

The review of paraclinical results will be based on the hospital protocol at the arrival of the patient and once every three days, and no other blood samples will be taken from the patient.

Method of measurement

Based on the sample taken from the patient

3

Description

The Vancouver Scar scale

Timepoint

In order to follow up after the first month, second month and sixth month after the end of the intervention, photographs will be taken of the light therapy site. To evaluate the scar, The Vancouver Scar scale will be used in 1, 3, and 6 months after the end of the intervention.

Method of measurement

Using The Vancouver Scar scale at 1, 3, 6 months after the end of the intervention

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Bioptron light therapy device (Bioptron AG, Wollerau, Switzerland) from Mehrgan Tejarat Carmania Company, made in Switzerland, in accordance with EEC/93/42 light with wavelength characteristics of 480 to 3400 nm, polarization percentage 95%, power density 40 mW/cm² and emits 4.2 J/cm² energy per minute. Light irradiation will be daily for 6 minutes in 10 sessions, with a distance of 10 cm from the wound (13). If the patient is discharged before the completion of the light therapy sessions or the wound closure, follow-up will be done for the participant's daily visit until the wound is closed and the light therapy sessions are completed. Before each session, the wound will be opened and washed with saline. 0% will be washed. After the participant is in a

comfortable position, the device will be placed towards the wound to shine the light. Then, according to the doctor's order, the usual treatment protocol for the wound will be implemented.

Category

Treatment - Devices

2

Description

Control group: Control group: the wound will be exposed to the open air for 6 minutes, then according to the doctor's order, the usual treatment protocol for the wound will be implemented.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Musa Kazem (a.s.) hospital

Full name of responsible person

Ehsaneh Najari Ardestani

Street address

Kaveh Avenue, Imam Musa Kazem (a.s.) hospital

City

Esfahan

Province

Isfahan

Postal code

8138894999

Phone

+98 31 3345 7670

Fax

+98 31 3345 8803

Email

ehsanehnajari@mail.mui.ac.ir

Web page address

<https://savaneh.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ehsaneh Najari Ardestani

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email
ehsanehnajari@mail.mui.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Ehsaneh Najari Ardestani

Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
Ale Mohammad Avenue

City
Esfahan

Province
Isfahan

Postal code
8193661971

Phone
+98 31 3345 7670

Email
ehsanehnajari@mail.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ehsaneh Najari Ardestani

Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

Street address

No. 22. Ale mohammad Ave. Esfahan

City
Esfahan

Province
Isfahan

Postal code
8193661971

Phone
+98 31 3462 3648

Fax

Email
ehsanehnajari@mail.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Ehsaneh Najari Ardestani

Position
Nurse

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
No. 22. Ale mohammad Ave. Esfahan

City
Esfahan

Province
Isfahan

Postal code
8193661971

Phone
+98 31 3462 3648

Fax

Email
ehsanehnajari@mail.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
We intend to publish it as an article

When the data will become available and for how long
We intend to publish it as an article

To whom data/document is available

We intend to publish it as an article

Under which criteria data/document could be used

We intend to publish it as an article

From where data/document is obtainable

We intend to publish it as an article

What processes are involved for a request to access data/document

We intend to publish it as an article

Comments

We intend to publish it as an article