

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of treatment with extracorporeal shock wave to improve the burn scar of limbs in burn patients

Protocol summary

Summary

Hypertrophic scars is one of the common complications after burn which would cause performance and appearance limitations. The existing surgical and conservative treatments are not always satisfying. Shock wave is a non-aggressive modality which has proven to have positive effects on scars and wound healing in a few conducted studies. The present study will evaluate the effect of shock wave on improving limb scars. This study is a non-randomized, uncontrolled, single-center stage 2 clinical trial. Participants are patients with an age of 18 years old or more with limb scars. Patients who has coagulopathy or heart pacemaker, pregnant women and patients with a history of chemotherapy and radiotherapy will be excluded from the study. 17 patients will be treated with chock wave for 6 sessions during 6 weeks. This study will be conducted in 2016 on patients who will refer to the burn unit of Imam Musa Kazem hospital for treatment. Before, right after, one month and three months after the intervention, pain and itching will be evaluated using VAS method and the appearance of scar will be evaluated using VSS method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012132091N1**

Registration date: **2017-02-06, 1395/11/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-06, 1395/11/18

Registrant information

Name

Mahsa Mazaheri

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-04-18, 1395/01/30

Expected recruitment end date

2016-12-20, 1395/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of treatment with extracorporeal shock wave to improve the burn scar of limbs in burn patients

Public title

Shock wave for treating burn scar

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being older than 18 years with limb burn scar caused by fire Exclusion criteria: having face, genitalia, thorax and neck scar; being pregnant for women; having coagulopathy and heart pacemaker; Undergoing chemotherapy and radiotherapy; having mental and physical disability; Not cooperating or not referring to continue the treatment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 17

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

Isfahan University of Medical Sciences

Street address

Hezar Jarib Boulevard

City

Isfahan

Postal code

Approval date

2016-04-13, 1395/01/25

Ethics committee reference number

IR.MUI.REC.1395.3.273

Health conditions studied

1

Description of health condition studied

burn scar

ICD-10 code

T20

ICD-10 code description

Burn and corrosion of head and neck

2

Description of health condition studied

burn scar

ICD-10 code

T21

ICD-10 code description

Burn and corrosion of trunk

3

Description of health condition studied

burn scar

ICD-10 code

T22

ICD-10 code description

Burn and corrosion of shoulder and upper limb, except wrist and hand

4

Description of health condition studied

burn scar

ICD-10 code

T23

ICD-10 code description

Burn and corrosion of wrist and hand

5

Description of health condition studied

burn scar

ICD-10 code

T24

ICD-10 code description

Burn and corrosion of hip and lower limb, except ankle and foot

6

Description of health condition studied

burn scar

ICD-10 code

T25

ICD-10 code description

Burn and corrosion of ankle and foot

Primary outcomes

1

Description

burn scar

Timepoint

before the intervention, right after the intervention, 1 month after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Visual Analogue Scale (VAS), Vancouver Scar Scale (VSS), Photographing the scar

Secondary outcomes

1

Description

burning pain

Timepoint

before the intervention, right after the intervention, 1 month after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Scar Appearance

Timepoint

before the intervention, right after the intervention, 1 month after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Vancouver Scar Scale (VSS)- photography

3

Description

Itching

Timepoint

before the intervention, right after the intervention, 1 month after the end of the intervention, 3 months after the end of the intervention

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

Treatment using STORZ MEDICAL AG device made in Switzerland by protocol 2 (Energy: 0.1 j/mm², 100 impulses per cm² and frequency of 4 Hz using focused probe) for 6 sessions, one session per week

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital, Department of physical medicine

Full name of responsible person

Dr. Parisa Taheri

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mansour Siavash

Street address

Isfahan University of Medical Sciences, Department of internal diseases

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan University of Medical Sciences

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

Isfahan University of medical Sciences

Full name of responsible person

Mahsa Mazaheri

Position

Resident of Physical medicine and Rehabilitation

Other areas of specialty/work

Street address

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Parisa Taheri

Position

Specialist

Other areas of specialty/work

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Position

Electronics Engineer

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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