

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Treatment of burn scars using Ablative CO2 fractional Laser and topical rapamycin (sirolimus)

Protocol summary

Summary

The prevalence of hypertrophic Scars following the burns is high (about 70%) And it still is one of the therapeutic challenge. Various treatments with different mechanisms have been suggested. one of the new and effective present treatments is using CO2 laser. Recently the role of Rampamycin ,collagen expression regulator, in hypertrophic scars treatment has been proposed and also this drug probably could affect dermal fibroblasts expression by inhibiting vascular endothelial growth factor.the aim of this study is to evaluate the effectiveness rate of fractional laser, Rapamycin topical cream and combination of both ways of laser and cream for burns scar treatment. in this clinical trial study 60 burning patients including men and women ,age range of 8-60 y/o,will be entered for pilot and they will be randomized by table of random numbers to three groups of 20 patients for treating by; only laser, only 1% Rapamycin local cream and combination of both ways.the inclusion criteria will be all of the patients with hypertrophic burning scar who refer to dermatology clinic of hazrate rasool hospital. Patients that suffer from psychological disorders whom unable to fill the concurrence paper, and pregnant or breast feeding ladies will be excluded from the study. blinding is impossible because of obvious intervention. Laser therapy will be done in three sessions with four weeks interval and Rapamycin cream will be added on lesions after each session. It will be recommended that to continue using the cream twice a day for 12 weeks. all the patients will be photographed by Visioface Before starting treatment, in each session and 6 months after the treatment thus scar improving rate and also probably adverse effects will be evaluated by associated objective and subjective factors.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052318210N7**

Registration date: **2017-09-10, 1396/06/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-09-10, 1396/06/19

Registrant information

Name

Elham Behrangi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

iran university of medical science

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment of burn scars using Ablative CO2 fractional Laser and topical rapamycin (sirolimus)

Public title

Treatment of burn scars using Ablative CO2 fractional Laser and topical rapamycin (sirolimus)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : All of patients with burn hypertrophic scar who will come to RasoulAkram hospital. Exclusion criteria: 1. do not fill the consent inform 2. pregnancy or breast feeding women 3. psychological disorders that could not understand or fill consent inform

Age

From **8 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

60 patients(men and women) will divide by computer table of random numbers to three (equal 20 patients in each) groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Iran University of Medical Sciences

Street address

Hemat Highway

City

Tehran

Postal code

Approval date

2017-02-12, 1395/11/24

Ethics committee reference number

IR.IUMS.REC 1395.95-04-204-30038

Health conditions studied

1

Description of health condition studied

Burn NOS

ICD-10 code

T30.0

ICD-10 code description

Burn of unspecified body region, unspecified degree

Primary outcomes

1

Description

contracture

Timepoint

every months in treatment period and 6 months after treatment completion

Method of measurement

Imaging of skin and scoring with Vancouver scar scale

2

Description

texture

Timepoint

every months in treatment period and 6 months after treatment completion

Method of measurement

Imaging of skin and scoring with Vancouver scar scale

Secondary outcomes

1

Description

satisfaction

Timepoint

every months in treatment period and 6 months after treatment completion

Method of measurement

Interview

2

Description

Skin colour

Timepoint

every months in treatment period and 6 months after treatment completion

Method of measurement

Imaging of skin and scoring with Vancouver scar scale

3

Description

Atrophy

Timepoint

every months in treatment period and 6 months after treatment completion

Method of measurement

Imaging of skin and scoring with Vancouver scar scale

Intervention groups

1

Description

Intervention in first group is CO2 Fractional laser, on burn scars. Device will set with skin types of patients, anatomic place and scars color and depth. laser will applied in three sections monthly.

Category

Treatment - Devices

2

Description

Intervention in second group is Rapamycin Cream. patients will treat with Rapamycin 1% Cream for 12 weeks.

Category

Treatment - Drugs

3

Description

Intervention in third group is combination therapy of CO2 Fractional laser(on burn scars that will applied in three sections monthly) added with Rapamayci 1% Cream.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Vice Chancellor for Research, Seyed Ali Javad Moosavi

Street address

Office of the Chancellor for Research, Iran University of Medical Sciences, Crossroad of Shahid Hemmat and Shahid Chamran Express Ways, Tehran, Islamic Republic of Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Science

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

Iran University of Medical Science

Full name of responsible person

Elham Behrangi

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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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