

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of Fractional CO2 Laser in Scar Revision of Alar Base in Patients under Rhinoplasty

Protocol summary

Study aim

Investigation of effect of fractional CO2 laser in scar revision of alar base in patients under Rhinoplasty.

Design

Patients are randomly divided into intervention and control groups and the study is design as a randomised, controlled, parallel group trial with double blinded outcome assessment. Randomisation will be centralised based on simple randomization method using random digits table.

Settings and conduct

Thirty patients in age group 18 to 50 years, with a history of open rhinoplasty and subsequent scarring in the alar base region, and 4 months had passed since their surgery at Imam Khomeini Hospital in Ahvaz are randomly divided by simple randomization method into intervention and control groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients with a history of open rhinoplasty, patients who had scarring in the alar base region following rhinolasty and no history of treatment for the alar base region scarring and four months have passed since the surgery; The exclusion criteria are patients with history of photosensitivity, keloid and hypertrophic scars, systemic disease and immunodeficiency, consumption of anticoagulant drugs and pregnancy and lactation.

Intervention groups

In the Intervention group, one session of laser treatment is performed with Fractional CO2 MORE-XEL -BISON-Korea with radiant characteristics: spot diameter 0.05 mm, pulse duration: 4 ms, laser power 12-14 watts and energy 48-56 mJ per pulse. In the control group, there is no intervention for them to treat the scar.

Main outcome variables

Improvement of scarring in the alar base region will be recorded and compared between two groups based on Vancouver Scar Scale before and 1 month after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200724048187N1**

Registration date: **2020-07-27, 1399/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-27, 1399/05/06**

Update count: **0**

Registration date

2020-07-27, 1399/05/06

Registrant information

Name

Farzin Hajizade

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3373 8383

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Fractional CO2 Laser in Scar Revision of Alar Base in Patients under Rhinoplasty

Public title

Effect of Fractional Laser in Scar Revision in Patients under Rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a history of open rhinoplasty Patients who had scarring in the alar base region following rhinoplasty Patients who had no history of treatment for the alar base region scarring Four months have passed since the surgery

Exclusion criteria:

Patients with history of photosensitivity Patients with history of keloid and hypertrophic scars Patients with history of systemic disease and immunodeficiency Consumption of anticoagulant drugs Pregnancy and lactation

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group and the odd numbers for the control group are considered. According to the number of patients, they are randomly assigned to one of the intervention or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are informed about the purpose and method of study. After receiving informed consent, they are blinded to the study groups to unify patients in terms of their empathy sense. Researchers responsible for data collection and analyses will also be blinded to the groups allocation for preventing personal viewpoint.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Research deputy, Ahvaz Jundishapur University Of Medical Sciences, Golestan Blvd.

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.AJUMS.REC.1398.235

Health conditions studied

1

Description of health condition studied

Scar after Rhinoplasty

ICD-10 code

L76

ICD-10 code description

Intraoperative and postprocedural complications of skin and subcutaneous tissue

Primary outcomes

1

Description

Improvement of scarring in the alar base region

Timepoint

Before and 1 month after treatment

Method of measurement

Vancouver Scar Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One session of laser treatment is performed with Fractional CO2 MORE-XEL -BISON-Korea with radiant characteristics: spot diameter 0.05 mm, pulse duration: 4 ms, laser power 12-14 watts and energy 48-56 mJ per pulse.

Category

Treatment - Devices

2

Description

Control group: There is no intervention for them to treat the scar.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Oral and Maxillofacial Surgery Clinic, Imam Khomeini Hospital, Ahvaz Jundishapur University of Medic

Full name of responsible person

Shahrokh Raisian

Street address

Oral and Maxillofacial Surgery Clinic, Imam Khomeini Hospital, Azadegan Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi, PhD

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Farzin Hajizadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Shahrokh Raisian

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Latest degree

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Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable