

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

Comparison of Incision Site Scarring in Upper Eyelid Blepharoplasty Using CO2 Laser Versus Cold Steel Scalpel: A Non-Randomized Pilot Clinical Trial Study

Protocol summary

Study aim

Comparison of Incision Site Scarring in Upper Eyelid Blepharoplasty Using CO2 Laser Versus Cold Steel Scalpel: A Non-Randomized Pilot Clinical Trial Study

Design

Preliminary clinical trial (Pilot), non-randomized, with parallel groups, on 20 patients. Patients will be assigned to two groups, "Scalpel" (control group) and "CO2 laser" (intervention group) based on personal preference.

Settings and conduct

A pilot, quasi-experimental study at Imam Khomeini Hospital (Dermatology Clinic), Ahvaz. Participants are divided into CO2 laser and scalpel groups. Surgery follows standard protocols using the Edge ONE device. Blinding: Blinded outcome assessment: The outcome assessor will be unaware of the treatment group (CO2 laser vs. scalpel) to minimize bias.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults aged 30–60 years eligible for upper eyelid blepharoplasty with no contraindicating ocular conditions. Exclusion criteria: Refusal to participate, coagulation disorders or anticoagulant use, previous eyelid surgery or trauma, active eyelid disease or infection, immunodeficiency, HIV, hepatitis B/C, diabetic neuropathy, or history of keloid formation.

Intervention groups

Intervention group: Upper eyelid blepharoplasty using a CO₂ laser (Edge One, Jeisys, South Korea) under local anesthesia (2% lidocaine with epinephrine 1:100,000), with wound closure using 6-0 nylon sutures. Control group: Upper eyelid blepharoplasty using a No. 15 surgical scalpel under local anesthesia (2% lidocaine with epinephrine 1:100,000), with wound closure using 6-0 nylon sutures.

Main outcome variables

Manchester Scar Scale score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230824059245N1**

Registration date: **2026-08-04, 1405/05/13**

Registration timing: **prospective**

Last update: **2026-08-04, 1405/05/13**

Update count: **0**

Registration date

2026-08-04, 1405/05/13

Registrant information

Name

Nader Pazayar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-11, 1405/05/20

Expected recruitment end date

2027-08-11, 1406/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Incision Site Scarring in Upper Eyelid Blepharoplasty Using CO2 Laser Versus Cold Steel Scalpel: A Non-Randomized Pilot Clinical Trial Study

Public title

Comparison of the effect of CO2 laser and scalpel surgery on scar quality in upper eyelid blepharoplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being a candidate for blepharoplasty according to the dermatologist's opinion and not having any eye problems that would prevent the surgery Age range between 30 and 60 years

Exclusion criteria:

Refusal to participate in the study Refusal to undergo blepharoplasty Refusal to undergo CO₂ laser blepharoplasty Coagulation disorders Current use of anticoagulant medications Abnormal coagulation test results (PT, PTT, INR, BT, or CT) Previous eyelid surgery History of eyelid trauma Active skin disease of the eyelid Active eyelid infection Immunodeficiency disorders Human immunodeficiency virus (HIV) infection Hepatitis B infection Hepatitis C infection Diabetes mellitus with neuropathy History of keloid formation

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Because of the nature of the surgical intervention, blinding of the surgeon and participants is not feasible. Therefore, the study is designed as a single-blind clinical trial. To implement blinding, standardized photographs will be obtained from all participants before surgery and at the 60-day follow-up under identical conditions (camera angle, distance, lighting, and patient position). All photographs will be coded with unique identification numbers, and no information regarding the intervention (CO₂ laser or cold steel scalpel) will be available to the outcome assessors. Scar quality will be evaluated using the Manchester Scar Scale by three independent assessors who are not involved in the surgical procedures or patient allocation and are fully blinded to the intervention received. In addition, the statistical analyst will receive a coded dataset (e.g., Group A and Group B) without access to treatment allocation, and

statistical analyses will be performed while remaining blinded to the intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical Sciences, Koi Golestan, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

6193673166

Approval date

2026-06-27, 1405/04/06

Ethics committee reference number

IR.AJUMS.REC.1405.132

Health conditions studied**1****Description of health condition studied**

Upper Eyelid Blepharoplasty

ICD-10 code

H02.4

ICD-10 code description

Ptosis of eyelid

Primary outcomes**1****Description**

Manchester Scar Scale score

Timepoint

Day 60 after surgery

Method of measurement

Scar score will be assessed on postoperative day 60 by three blinded assessors using the Manchester Scar Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Upper eyelid blepharoplasty is performed using a CO₂ laser (Edge One, Jeisys, South Korea). An antibiotic-ointment-soaked eye shield is used for ocular protection. Laser settings include Continuous Wave mode, 100f tip, and 1 W power for the initial incision, and 3 W power for tissue excision. Local anesthesia is administered using 2% lidocaine with epinephrine (1:100,000), and the wound is closed with 6-0 nylon simple interrupted sutures.

Category

Treatment - Surgery

2

Description

Control group: Upper eyelid blepharoplasty is performed using a No. 15 surgical scalpel. Hemostasis is achieved using an electrocautery device in coagulation mode. Local anesthesia is administered using 2% lidocaine with epinephrine (1:100,000), and the wound is closed with 6-0 nylon simple interrupted sutures.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital., Dermatology Clinic

Full name of responsible person

Nader Pazyar

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Imam Khomeini Hospital., 24 Meters., Azadegan St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdollah Rafiei

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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

Nader Pazyar

Position

Associate Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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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

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

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

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

Data Dictionary

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