Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 CO_2 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 Pazyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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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 CO_2 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 (CO_2 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

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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 CO_2 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 scientific inquiries

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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