

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Clinical Outcomes of CO2 Laser Assisted Upper Lid Blepharoplasty by Two Different Methods: a Randomized Clinical Trial Study

Protocol summary

Study aim

Comparison of Post Surgical Complications, Treatment Results and Patient Satisfaction of Two Different Laser Assisted Blepharoplasty of Upper Lids

Design

Randomized Clinical Trial with Parallel Group of 21 Patients, Double Blinded on Patient and Outcome assessment

Settings and conduct

In this Study, Upper Lid Bilateral Blepharoplasty will be operated in Patients with Mild to Severe Bilateral Ptosis referred to the Maxillofacial Surgery Department of Imam Khomeini Hospital. All Surgeries will be performed by the same Surgeon and the Surgical Position was randomly assigned using Digital Randomization. After Local Anesthesia, the Amount of Extra Tissue will be determined by the Pinch's Technique. On One Side, the Scalpel 15 and on the other Side the CO2 Laser is used for cutting the Skin. Other Surgical Procedures will be Laser-based. In the Area under Laser Surgery for cutting the Skin, the Program Settings 1 (Continuous Emission / Ultrapulse Mode / Power 3 W) and for Muscle cutting, the Program Settings 2 (Continuous Emission / Regular Mode / Power 9 W) will be used. After the Supratarsal Incision, the Skin and Subcutaneous Tissue are removed and the Medial Fatty Tissue will be cutted.

Participants/Inclusion and exclusion criteria

inclusion criteria: Normal Ophtalmic Examination and Bilateral Mild to Sever Ptosis of Upper Lids exclusion criteria: Anticoagulant therapy, Coagulopathy, Disorders causing Peripheral Neuropathy such as Diabetes Mellitus, History of Trauma or Surgery of Upper ILids and Skin Disorders

Intervention groups

In Each Patient, Skin Incision was made by the Scalpel no.15 on One Side and the CO2 Laser on the Opposite Side. Other Surgical Procedures will be Same and Laser-

based. Each Patient will receive both Treatment Modalities.

Main outcome variables

Edema, Ecchymosis and Erythema Days of 1, 3, 7, 14 and 30 after Surgery and Scar at the Field of Surgery after 60 Days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180302038917N1**

Registration date: **2018-11-13, 1397/08/22**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-13, 1397/08/22**

Update count: **0**

Registration date

2018-11-13, 1397/08/22

Registrant information

Name

milad Alikazemi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2018-12-22, 1397/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Clinical Outcomes of CO2 Laser Assisted Upper Lid Blepharoplasty by Two Different Methods: a Randomized Clinical Trial Study

Public title
Comparison of CO2 Laser Assisted Upper Lid Blepharoplasty by Two Different Methods

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Normal Ophthalmic Examination Bilateral Mild to Sever Ptosis of Upper Lids
Exclusion criteria:
Anticoagulant Therapy Coagulopathy Disorders Causing Peripheral Neuropathy such as Diabetes Mellitus History of Trauma or Surgery of Upper Lids Skin Disorders

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **21**
More than 1 sample in each individual
Number of samples in each individual: **2**
each one of the left and right upper lid will receive one of two determined surgical modalities

Randomization (investigator's opinion)
Randomized

Randomization description
Through Software, 21 series (as 21 patients) are randomized between numbers of 1 (as the Blade and Laser group) or 2 (the Laser group alone). (www.randomizer.org). In each patient, selected number will determine surgical approach of the right eye. The left eye will be treated by the opposite approach.

Blinding (investigator's opinion)
Double blinded

Blinding description
Although Each Patient will be informed about the Application of Two Surgical Methods , the Treatment Modality of Each Lid will not be determined. Post Operation Instructions will be Same in Two Lids. The Person Responsible for Evaluation of Treatment Results in Predetermined Time Sequence will score each Lid Blinded on Treatment Modality.

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

Oral and Maxillofacial Surgery Department, Imam Khomeini Hospital, Azadegan street

City

Ahvaz

Province

Khuzestan

Postal code

6193673166

Approval date

2017-12-27, 1396/10/06

Ethics committee reference number

IR.AJUMS.REC.1396.766

Health conditions studied

1

Description of health condition studied

Bilateral Mild to Sever Ptosis of Upper lids

ICD-10 code

H02.4

ICD-10 code description

Ptosis of eyelid

Primary outcomes

1

Description

scar at the field of surgery

Timepoint

after 60 days

Method of measurement

Manchester scar scale

2

Description

Edema

Timepoint

days of 1, 3, 7, 14 and 30 after surgery

Method of measurement

Likert scale

3

Description

Ecchymosis

Timepoint

days of 1, 3, 7, 14 and 30 after surgery

Method of measurement

Likert scale

4

Description

Erythema

Timepoint

days of 1, 3, 7, 14 and 30 after surgery

Method of measurement

Likert scale

Secondary outcomes

1

Description

Patients satisfaction

Timepoint

after 60 days

Method of measurement

Likert Scale

Intervention groups

1

Description

Intervention group 1: On One Side is used for cutting the Skin. Other Surgical Procedures will be Laser-based.

Category

Treatment - Surgery

2

Description

Intervention group 2: On the other Side the CO2 Laser is used for cutting the Skin. Other Surgical Procedures will be Laser-based. In the Area under Laser Surgery for cutting the Skin, the Program Settings 1 (Continuous Emission / Ultrapulse Mode / Power 3 W/tip size 0.2) and for Muscle cutting, the Program Settings 2 (Continuous Emission / Regular Mode / Power 9 W/tip size 0.2) will be used.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center**Name of recruitment center**

Imam Khomeini Hospital

Full name of responsible person

Mohammad Reza Fallahi

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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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

Milad Alikazemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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