Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Assissted 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 cuttered.

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 lLids 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 receiv 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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+98 61 3333 1799

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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 Ophtalmic 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

Khouzestan

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 satifaction
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
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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