

# 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)

##### Phone

+98 61 3333 1799

##### Email address

alikalazemi.m@ajums.ac.ir

##### 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

**Street address**

Azadegan street

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6193673166

**Phone**

+98 61 3322 2818

**Email**

fallahi.h@ajums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

mohammad badavi

**Street address**

Azadegan street, Imam Khomeini Hospital

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+98 61 3373 8383

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badavi-m@ajums.ac.ir

**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**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Hamid Reza Fallahi

**Position**

Assistant professor

**Latest degree**

Specialist

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**Full name of responsible person**

Milad Alikazemi

**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Oral and Maxillofacial Surgery

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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