

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation and comparison of side effects and satisfaction of patient and physician in minimally invasive inferior phenol blepharopeeling versus blepharoplasty without peeling for rejuvenation of lower lids

Protocol summary

Study aim

comparison of side effects and satisfaction of patient and physician in minimally invasive inferior phenol blepharopeeling versus blepharoplasty without peeling.

Design

A trial with parallel group design was conducted on 30 patients with lower lids herniation. The trial was single blind in which the person who evaluated the results was kept blind. The trial was conducted between October 2017 and October 2018. The period of follow up was two months.

Settings and conduct

A total of 30 patients who referred to Alzahra Hospital in Isfahan in 1396 were randomly divided into two groups of blepharopeeling and blepharoplasty without peeling. All Surgeries were performed by the same surgeon. Before and 2 months after surgery photograph was taken from the patient's face. Each photograph was compared before and after surgery by two physicians and the degree of satisfaction was recorded as "low 25%, average 50%, good 75%, and excellent 100%."

Participants/Inclusion and exclusion criteria

Inclusion criteria: skin type of 1-3 based on Fitz Patrick criteria; presentation of herniation of under eyelid located fatty tissue; lacking of tear trough deformity; over 40 years old of age; patients' willingness for participation in the study. Non-inclusion criteria: any history of previous local treatment; psychological diseases ; severe aging related changes in their inferior eyelid.

Intervention groups

Intervention group 1: The group of Blepharopeeling, which is treated by minimally invasive blepharoplasty with the addition of phenol peeling. Intervention group 2: Blepharoplasty group in which blepharoplasty without peeling of lower lids is used.

Main outcome variables

Erythema; Hypopigmentatio; Hyperpigmentation; scar; Hematoma; Granuloma; Infection; Swelling; Bruises; Cellulitis; Asymmetry; Ptosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181216042009N1**

Registration date: **2019-01-20, 1397/10/30**

Registration timing: **retrospective**

Last update: **2019-01-20, 1397/10/30**

Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Mahboubeh Talakoub

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2017-10-02, 1396/07/10

Actual recruitment end date

2018-11-21, 1397/08/30

Trial completion date

2018-11-21, 1397/08/30

Scientific title

Evaluation and comparison of side effects and satisfaction of patient and physician in minimally invasive inferior phenol blepharopeeling versus blepharoplasty without peeling for rejuvenation of lower lids

Public title

Effect of peeling with phenol to rejuvenate the lower eyelids

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Skin type of 1-3 based on Fitz Patrick criteria presentation of herniation under eyelid located fatty tissue Absence of tear trough deformity over 40 years of age patients' willingness for participation the study

Exclusion criteria:

Patients who presented any history of previous local treatment history of psychological diseases severe aging related changes in the inferior eyelid

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is performed in a simple way. Based on the random number tables, the patients are divided into two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The person responsible for evaluation of treatment results in predetermined time sequence will score patients without knowing the 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 Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

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Province

Isfahan

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8174675731

Approval date

2017-07-29, 1396/05/07

Ethics committee reference number

IR.MUI.REC.1396.3.644

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

Fat herniation of lower eyelids

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Rate of the patient's satisfaction for decrease fat herniation of lower lids

Timepoint

Two months after operation

Method of measurement

Questionnaire

2**Description**

Rate of the patient's satisfaction for symmetry

Timepoint

Two months after operation

Method of measurement

Questionnaire

3**Description**

Rate of the patient's satisfaction for esthetics

Timepoint

Two months after operation

Method of measurement

Questionnaire

4

Description

Rate of the patient's satisfaction for eyelid prolapse

Timepoint

Two months after operation

Method of measurement

Questionnaire

5

Description

Rate of the patient's general satisfaction

Timepoint

Two months after operation

Method of measurement

Questionnaire

6

Description

Rate of the physician's satisfaction with the lower eyelid flaccidity decrease

Timepoint

Two months after operation

Method of measurement

Observation

Secondary outcomes

1

Description

Periorbital erythema

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

2

Description

Hypopigmentation

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

3

Description

Hyperpigmentation

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

4

Description

Scar

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

5

Description

Hematoma

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

6

Description

Granuloma

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

7

Description

Infection

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

8

Description

Dry eye syndrome

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

9

Description

Edema

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

10

Description

Bruising

Timepoint

Daily up to one week and then 2 weeks and 2 months

after operation

Method of measurement

Visit, history and physical examination

11

Description

Loss of vision

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

12

Description

Diplopia

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

13

Description

Lagophthalmos

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

14

Description

Asymmetry

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

15

Description

Ptosis

Timepoint

Daily up to one week and then 2 weeks and 2 months after operation

Method of measurement

Visit, history and physical examination

16

Description

Pain

Timepoint

Daily up to one week and then 2 weeks and 2 months after treatment start

Method of measurement

Visit, history and physical examination

Intervention groups

1

Description

Intervention group: After cleaning the face and injecting the local anesthetic in the lower eyelid region in the blepharopeeling group, peeling is performed in lower periocular region using phenol 89% and a cotton applicator until a white layer is formed. The skin and underlying muscle were incised superficially using bisturi no 15, and then underlying fat tissue excised using finger pressure, bishop forceps and curve forceps. Following excision of adequate fat tissue, remained stalk was burned using cautery. This process was performed for all marked fat pads Then, a simple suture of ethilon 5.0 is used to close the gap.

Category

Treatment - Surgery

2

Description

Control group: After injecting the local anesthetic in the blepharoplasty group, the skin and underlying muscle were incised superficially using bisturi no 15, and then underlying fat tissue excised using finger pressure, bishop forceps and curve forceps. Following excision of adequate fat tissue, remained stalk was burned using cautery. This process was performed for all marked fat pads Then, a simple suture with ethilon 5.0 is used to close the gap.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital ,Isfahan

Full name of responsible person

Dr.Mahboobeh Talakoub

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Dermatology Department, Alzahra hospital, Sofe Blvd, Isfahan.

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Sponsors / Funding sources

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Talakoob

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Ali Asilian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboobeh Talakoob

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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