Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 blephapeeling 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: Belpharoplasty 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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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.
City
Isfahan
Province
Isfehan
Postal code
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

Lagophtalmos

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

Street address

Dermatology Department, Alzahra hospital, Sofe Blvd, Isfahan.

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Sponsors / Funding sources

1

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

Contact

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
Dermatology

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Person responsible for updating data

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Esfahan University of Medical Sciences

Full name of responsible person
Mahboobeh Talakoob

Position
Resident

Latest degree
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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