

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation and comparison of side effects and satisfaction of patient and physician in Micropunch Blepharopeeling versus blepharoplasty of the Upper Eyelids for Periorbital Rejuvenation in patients who referred to Alzahra hospital in 2016

Protocol summary

Summary

Objectives: Evaluation and comparison of side effects and satisfaction of patient and physician in Micropunch Blepharopeeling versus blepharoplasty of the Upper Eyelids for Periorbital Rejuvenation in patients who referred to Alzahra hospital in 2016. The present study is a kind of controlled clinical pilot study in which 20 patients refer to the skin clinics affiliated to Esfahan University of Medical Science for periorbital rejuvenation. They are easily and nonrandomly included in the study and are randomly allocated to treatment groups of micropunch blepharopeeling and blepharoplasty. After cleaning the face and injecting the local anesthetic in the upper eyelid region in the blepharopeeling group, peeling is performed in all the periocular region using phenol 89% and a cotton applicator until a white layer is formed. With a pair of iris scissors then, depending on the patient's skin thickness, 5-20 scissors cut, each 3-5 mm wide, are performed in a network model in the upper eyelid. The cuts are not sutured. They are however spontaneously epithelialized instead. After injecting the local anesthetic in the blepharoplasty group, the cuts are superficially performed with surgery blade NO.15 through the epiderm of the skin which have previously been marked are taken off. Hemostasis is performed with a cauter and the fats are taken out and cauterized. Both groups of the patients are visited for complications and the rate of the patient's satisfaction is rated 2 months after operation based on a 5 score scale. The level of the physician's satisfaction is registered pre-operatively and 2 months after operation using relevant photographs by 2 separate physicians on the low, medium, good and high scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016110330682N1**

Registration date: **2016-12-07, 1395/09/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

Behzad Bafandeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

b.bafandeh@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of side effects and satisfaction of patient and physician in Micropunch Blepharopeeling versus blepharoplasty of the Upper Eyelids for Periorbital Rejuvenation in patients who referred to Alzahra hospital in 2016

Public title

Study of the effect of phenol peeling blephroplasty for the periocular rejuvenation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age over 40 years; skin type : Fitzpatrick I-III; skin thickness : thin to medium; periorbitally scattered wrinkles; upper eyelid medial or lateral mild- to- medium Ptosis and informed Satisfaction to participate in the study Exclusion criteria: previous local treatment; patients dissatisfaction.

Age

From **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**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

Postal code**Approval date**

2016-05-04, 1395/02/15

Ethics committee reference number

IR.MUI.REC.1395.3.301

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

Blepharochalasis

ICD-10 code

H02.3

ICD-10 code description

Blepharochalasis

Primary outcomes**1****Description**

rate of the patient's satisfaction for eyelid prolapse

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 physician's satisfaction with the upper eyelid flaccidity decrease

Timepoint

two months after operation

Method of measurement

observation

4**Description**

rate of the patient's satisfaction for esthetics

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

Secondary outcomes

1

Description

periorbital erythema

Timepoint

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

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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 treatment start

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**

After cleaning the face and injecting the local anesthetic in the upper eyelid region in the blepharopeeling group, peeling is performed in all the periocular region using phenol 89% and a cotton applicator until a white layer is formed. With a pair of iris scissors then, depending on the patient's skin thickness , 5-20 scissors cuts , each 3-5 mm wide, are performed in a network model in the upper eyelid.the cuts are not sutured . they are however spontaneously epithelialized instead.

Category

Treatment - Surgery

2**Description**

After injecting the local anesthetic in the blepharoplasty group, the cuts are superficially performed with surgery blade NO.15 through the epiderm of the skin which have previously been marked are taken off. Hemostasis is performed with a cauter and the fats are taken out and cauterized and the wound is sutured.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan Al Zahra Hospital

Full name of responsible person

Dr Behzad Bafandeh

Street address

Department of dermatology, Al Zahra Hospital ,
Soffeh Blvd

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of research of Isfahan University of Medical
Sciences

Full name of responsible person

Dr Mehdi Nemat bakhsh

Street address

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

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of research of Isfahan University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Isfahan University of Medical Science

Full name of responsible person

Dr Behzad Bafandeh

Position

resident of dermatology

Other areas of specialty/work

Street address

Department of dermatology, Al Zahra Hospital ,
Soffeh Blvd

City

Isfahan

Postal code**Phone**

+98 31 3668 5555

Fax**Email**

b.bafandeh@resident.mui.ac.irbehzad.bafandeh@gm
ail.combehzad_bafandeh@yahoo.com

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

Isfahan University of Medical Science _ Skin disease
and Leishmaniasis Research Center, Isfahan Univ

Full name of responsible person

Dr Ali Asillian

Position

professor

Other areas of specialty/work**Street address**

Department of dermatology, Al Zahra Hospital ,
Soffeh Blvd

City

Isfahan

Postal code**Phone**

+98 31 3620 2020

Fax**Email**

asillian@med.mui.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Department of dermatology, Al Zahra Hospital ,
Soffeh Blvd

Full name of responsible person

Dr Behzad Bafandeh

Position

resident of dermatology

Other areas of specialty/work**Street address**

Department of dermatology, Al Zahra Hospital ,
Soffeh Blvd

City

Isfahan

Postal code**Phone**

+98 31 3620 2020

Fax**Email**

b.bafandeh@resident.mui.ac.irbehzad.bafandeh@gm
ail.combehzad_bafandeh@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty