Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Nov 2026

Evaluating the Effect of Lateral Osteotomy on Intraocular Pressure

Protocol summary

Study aim
Evaluating the Effect of Lateral Osteotomy on Intraocular Pressure
Design
Controlled clinical trial with parallel groups with out blinded design of 96 patients.
Settings and conduct
Intraocular Pressure measurement in all patients with Goldmann tonometer before and after the surgery in 3 runs
Participants/Inclusion and exclusion criteria
All patients that candidated for Rhinoplasty Surgery that refer to ENT Clinic of Taleghani Hospital in Tehran
Intervention groups
Intraocular Pressure measurement in all patients before and after surgery
Main outcome variables
No effect of time on Intraocular Pressure after surgery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200420047142N1**
Registration date: **2020-05-29, 1399/03/09**
Registration timing: **retrospective**

Last update: **2020-05-29, 1399/03/09**
Update count: **0**
Registration date
2020-05-29, 1399/03/09

Registrant information
Name
Atieh Zahedi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 17 3254 3580
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-12, 1398/07/20
Expected recruitment end date
2020-03-19, 1398/12/29
Actual recruitment start date
2019-10-12, 1398/07/20
Actual recruitment end date
2020-02-18, 1398/11/29
Trial completion date
2020-03-19, 1398/12/29

Scientific title
Evaluating the Effect of Lateral Osteotomy on Intraocular Pressure

Public title
Evaluating the Effect of Osteotomy on Intraocular Pressure
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The patients that candidated for Rhinoplasty Surgery and refer to ENT Clinic of Taleghani Hospital in Tehran in the year 98
Exclusion criteria:
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information

Sample size
Target sample size: **96**
Actual sample size reached: **96**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not 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 Shahid Beheshti University of Medical Sciences
Street address
No. 1, Salehi Ave., Golshahr Blvd., Gorgan Town
City
Gorgan
Province
Golestan
Postal code
4916745436
Approval date
2019-10-08, 1398/07/16
Ethics committee reference number
IR.SBMU.MSP.REC.1398.691

Health conditions studied

1

Description of health condition studied
Intraocular Pressure
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Increased Intraocular Pressure after lateral Osteotomy
Timepoint
Intraocular Pressure measurement before surgury and 1,7,30 days after the surgery
Method of measurement
Goldmann Applanation Tonometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intraocular Pressure measurement after Rhinoplasty surgery with lateral osteotomy with Goldmann tonometer on days 1 and 7 and 30
Category
Prevention

2

Description
Control group: Intraocular Pressure measurement before Rhinoplasty surgery with Goldmann tonometer
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Atieh Zahedi
Street address
Araabi Ave., Daneshjoo Blvd., Tehran Town
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taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Araabi Ave., Daneshjoo Blvd., Tehran Town
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Atiyeh Zahedi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Share Intraocular Pressure measurement

When the data will become available and for how

long

Start the access period 1 year after printing the results

To whom data/document is available

Researchers working in academic Institutions

Under which criteria data/document could be used

In academic research

From where data/document is obtainable

Refer to atiyeh.zahedi@gmail.com and Send a request with a valid e-mail 00989111776883

What processes are involved for a request to access data/document

Send a request with a valid e-mail to atiyeh.zahedi@gmail.com

Comments