Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparision of the effect of dexamethasone and tranexamic acid on postrhinoplasty periorbital edema and ecchymosis

Protocol summary

Summary

Usually dexamethasone has been suggested for reducing the postrhinoplasty periorbital edema and ecchymosis.This study will compare dexamethasone and tranexamic asid effect on periorbital edema and ecchymosis after rhinoplasty.In a double blind clinical trial,45 rhinoplasty patients will be randomized in 3 groups.Group 1 will receive dexamethasone and group 2 will receive tranexamic acid and group 3 will receive both dexamethasone and tranexamic acid.Injection for all groups is a dose of drug 1 hour before surgery and 3 doses per 8 hours after rhinoplasty.Patients will be evaluated postoperatively at 1,3,7 days for periorbital edema and ecchymosis by GURLEK standard scales.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110224842N1**
Registration date: **2015-12-15, 1394/09/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-15, 1394/09/24

Registrant information

Name

Hosein Ghanepur

Name of organization / entity

BABOL UNIVERSITY OF MEDICAL SCIENCES

Country

Iran (Islamic Republic of)

Phone

+98 11 3229 1408

Email address

h.ghanepur@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of BABOL UNIVERSITY OF MEDICAL SCIENCES

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparision of the effect of dexamethasone and tranexamic acid on postrhinoplasty periorbital edema and ecchymosis

Public title

Comparision of the effect of dexamethasone and tranexamic acid on postrhinoplasty periorbital edema and ecchymosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:candidates aged 18-39 for rhinoplasty ;similar nasal deformity ;need for hump removal and lateral and medial osteotomy ;ASA=1 Exclusion criteria:history of peptic ulcer;diabetes mellitus;cardiovascular disease;thromboembolism;pregnancy;renal failure;seizure;anticoagulants;herpes simplex;tuberculosis;glaucoma;active infection;psychiatric problems;coagulation disorders;sensitivity to corticostroids and tranexamic acid ;need for septoplasty

Age
From **18 years** old to **39 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double 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, Deputy Of Research and Technology, BABOL UNIVERSITY OF MEDICAL SCIENCES
Street address
Ethics committee, Deputy of Research and Technology, BABOL UNIVERSITY OF MEDICAL SCIENCES, IRAN
City
Babol
Postal code
Approval date
2015-10-20, 1394/07/28
Ethics committee reference number
MUBABOL.REC.1394.158

Health conditions studied

1

Description of health condition studied
Postrhinoplasty periorbital edema and ecchymosis
ICD-10 code
y84
ICD-10 code description
Other medical procedures as the cause of abnormal reaction of the patient,or of later complication,without mention of misadventure at the time of the procedure

Primary outcomes

1

Description
Periorbital edema
Timepoint
1,3,7 days after rhinoplasty
Method of measurement
GURLEK standard scales

2

Description
Periorbital ecchymosis
Timepoint
1,3,7 days after rhinoplasty
Method of measurement
GURLEK standard scales

Secondary outcomes

empty

Intervention groups

1

Description
Group 1(Dexamethasone intervention): IV injection a dose of 8mg,one hour before surgery and then 3 doses per 8 hours after surgery
Category
Treatment - Drugs

2

Description
Group 2(tranexamic acid):IV injection a dose of 10 mg/kg,one hour before and 3 doses every 8 hours after surgery.
Category
Treatment - Drugs

3

Description
Group 3(Dexamethasone and tranexamic acid intervention):IV injection a dose of 8 mg dexamethasone and a dose of 15 mg/kg tranexamic acid,one hour before surgery and then 3 doses of both drugs per 8 hours after surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Babol Shahid Beheshti Hospital

Full name of responsible person
Hosein Ghanepur
Street address
Maxillofacial Surgery Ward, Shahid Beheshti Hospital, BABOL UNIVERSITY OF MEDICAL SCIENCES, IRAN
City
Babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of BABOL UNIVERSITY OF MEDICAL SCIENCES
Full name of responsible person
Ali Bizhani
Street address
Vice chancellor for research of BABOL UNIVERSITY OF MEDICAL SCIENCES, IRAN
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research of BABOL 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
BABOL UNIVERSITY OF MEDICAL SCIENCES
Full name of responsible person
Hosein Ghanepur
Position
Resident
Other areas of specialty/work
Street address
Maxillofacial Surgery Ward, Dental School, BABOL UNIVERSITY OF MEDICAL SCIENCES, IRAN
City
Babol
Postal code
Phone
+98 11322914089
Fax
+98 11 3229 1093
Email
h.ghanepur@mubabol.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
BABOL UNIVERSITY OF MEDICAL SCIENCES
Full name of responsible person
Mohammad Mehdizadeh
Position
Maxillofacial Surgeon.Assistant Professor
Other areas of specialty/work
Street address
Maxillofacial Surgery Ward, BABOL UNIVERSITY OF MEDICAL SCIENCES, IRAN
City
Babol
Postal code
Phone
+98 11322914089
Fax
+98 11 3229 1093
Email
dr.rmohammad@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
BABOL UNIVERSITY OF MEDICAL SCIENCES
Full name of responsible person
Hosein Ghanepur
Position
Resident of Maxillofacial Surgery
Other areas of specialty/work
Street address
Maxillofacial Surgery Ward, BABOL UNIVERSITY OF MEDICAL SCIENCES,Babol, IRAN
City
Babol
Postal code
Phone
+98 11322914089
Fax
+98 11 3229 1093
Email
h.ghanepur@mubabol.ac.ir
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