

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

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Summary

Usually dexamethasone has been suggested for reducing the postrhinoplasty periorbital edema and ecchymosis. This study will compare dexamethasone and tranexamic acid 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.

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

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

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Country

Iran (Islamic Republic of)

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Email address

Scientific title

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

Public title

Comparison 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 corticosteroids 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

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

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Ali Bizhani

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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 sourceVice 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**

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Full name of responsible person

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Resident

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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