

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A clinical trial comparing the effect of three-doses of dexamethasone with a single-dose on intraoperative bleeding, blood pressure, operation time, edema and ecchymosis in patients who performed rhinoplasty.

Protocol summary

Summary

In most rhinoplasty surgeries, a corticosteroid is used to reduce inflammatory complications. Due to the severe complications of rhinoplasty, this study was designed with the aim of comparing the three doses of dexamethasone with a single-dose of dexamethasone in reducing intraoperative bleeding, blood pressure, operation time, edema and ecchymosis due to rhinoplasty. Patients who are going to be studied are between 18 and 30 years old and do not have a history of diseases such as hypertension, heart diseases and diabetes, also they are not smokers or alcoholic either. In this clinical trial, among the candidates for rhinoplasty surgery, 100 patients will be selected and randomly be divided into two groups of 50 people. All patients will sign informed consent. This intervention about prescribing of drugs is so that only the doctor is aware of how to prescribe drugs. In both groups patients will be use the same venous dexamethasone ampoules(8 mg per kg). In the first group, a single dose will be injected before surgery and in the second group, three doses of dexamethasone will be injected so that the first dose will be taken like the first group, the second dose 8 hours after the operation, and the third dose 8 hours after the second injection. During the operation intraoperative bleeding, operation time, blood pressure and degree of eyelid edema and ecchymosis of the soft tissue around the eye will be recorded on the second day. In all patients, postoperative edema and ecchymosis, will be used a 0-4 scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014011316195N1**
Registration date: **2014-05-11, 1393/02/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-11, 1393/02/21

Registrant information

Name

Mohammad Khakzad

Name of organization / entity

Shahid Beheshti hospital

Country

Iran (Islamic Republic of)

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+98 11 1225 6285

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khakzad@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Babol University of Medical Sciences

Expected recruitment start date

2013-05-22, 1392/03/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparing the effect of three-doses of dexamethasone with a single-dose on intraoperative

bleeding, blood pressure, operation time, edema and ecchymosis in patients who performed rhinoplasty.

Public title

Comparing the effect of three-doses of dexamethasone with a single-dose in reducing intraoperative bleeding, blood pressure, operation time, edema and ecchymosis induced by rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients are in the age range of 18 to 30 years; they do not have any history of diseases such as hypertension; heart diseases, diabetes; smoking or drinking alcohol. Exclusion criteria: Patients are not in the age range of 18 to 30 years; or have any history of diseases such as hypertension, heart diseases, diabetes; smoking or drinking alcohol.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences- Ganj afrooz

Street- Babol- Iran

City

Babol

Postal code

Approval date

2013-04-21, 1392/02/01

Ethics committee reference number

2306

Health conditions studied

1

Description of health condition studied

Plastic Surgery

ICD-10 code

Z41

ICD-10 code description

Procedures for purposes other than remedying health state

Primary outcomes

1

Description

Degree of eyelid edema

Timepoint

On the second day after surgery

Method of measurement

Clinical

2

Description

Ecchymosis of the soft tissue around the eyes

Timepoint

On the second day after surgery

Method of measurement

Clinical

3

Description

Operation time

Timepoint

During the operation

Method of measurement

Clinical

4

Description

Bleeding amount

Timepoint

During the operation

Method of measurement

Clinical

5

Description

Systolic and diastolic blood pressure

Timepoint

During the operation

Method of measurement

Clinical

Secondary outcomes

empty

Intervention groups

1

Description

Case group receive three doses of dexamethasone (8mg/kg), the first dose prior to surgery; Second dose inject 8 hours after surgery and the third dose carry 8 hours after the second injection.

Category

Treatment - Drugs

2

Description

In the case group before surgery, a single-dose of dexamethasone (8mg/kg) will be injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehregan Hospital

Full name of responsible person

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology of Babol University of Medical Sciences

Full name of responsible person

Dr. Aliakbar Moghadamnia

Street address

Babol University of Medical Sciences- Ganj afrooz Street- Babol- Iran

City

Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research and Technology 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

Neda Amani

Position

Expert

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mohammad Khakzad

Position

Plastic surgery subspecialist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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