# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**

+98 11 1225 6285

**Email address**

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**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**
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Babol University of Medical Sciences
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Plastic surgery subspecialist
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## 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*