

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of the effect of Dexamethasone and Ketorolac, separately on post rhinoplasty edema and ecchymosis

Protocol summary

Study aim

Comparison of effects of Dexamethasone and Ketorolac on edema and ecchymosis after rhinoplasty

Design

A clinical trial with 2 intervention groups, with parallel groups, randomized, phase 2 on 60 patients. Block randomization is done through computer generated codes by www.sealedenvelope.com.

Settings and conduct

Patients who are candidate for rhinoplasty and referred to ENT Clinic of Loqman Hospital in Tehran will be evaluated. Then, if the patients fulfilled all the inclusion criteria, will be randomly (by using block randomization) divided into two groups (ketorolac or dexamethasone). After surgery, patients will receive dexamethasone or ketorolac according to the treatment plan. After 7 days of surgery, a photo of the patient's face (with a digital camera) is given to two otolaryngologists, and edema and ecchymosis will be determined using the standard tools of the grading system (zero to four points).

Participants/Inclusion and exclusion criteria

Patients who are candidate for rhinoplasty and aged 18-45 years will be enrolled. Patients with a history of nasal surgery, need for septoplasty, need for osteotomy, heart failure, drug abuse, history of hypersensitivity to non-steroidal anti-inflammatory drugs, ulcerative gastrointestinal disease, diabetes, asthma, pulmonary failure, renal failure, and history of nasal fracture will be excluded.

Intervention groups

After the surgery, in intervention group 1, patients received intravenous dexamethasone (8 mg), one dose before and three doses every 8 hours after surgery. In intervention group 2, patients received one dose intramuscular ketorolac (30mg) after induction of anesthesia and two other doses every 8 hours.

Main outcome variables

Severity of Edema; Severity of Ecchymosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055606N1**

Registration date: **2022-09-20, 1401/06/29**

Registration timing: **retrospective**

Last update: **2022-09-20, 1401/06/29**

Update count: **0**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

alireza moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6522 4135

Email address

alirezamoradi_md@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-11, 1401/04/20

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

2022-07-11, 1401/04/20

Actual recruitment end date

2022-07-22, 1401/04/31

Trial completion date

2022-07-22, 1401/04/31

Scientific title

Comparison of the effect of Dexamethasone and Ketorolac, separately on post rhinoplasty edema and ecchymosis		Name of ethics committee Ethics Committee of Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Tehran	
Public title	Effect of dexamethasone and ketorolac on edema and ecchymosis after rhinoplasty	Street address	Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway
Purpose	Treatment	City	Tehran
Inclusion/Exclusion criteria		Province	Tehran
Inclusion criteria:	Age 18-45 years Patients who are candidate for rhinoplasty	Postal code	1333635445
Exclusion criteria:	History of previous nose surgery Need for septoplasty Need osteotomy Heart failure Drug abuse History of hypersensitivity to non-steroidal anti-inflammatory drugs History of ulcerative gastrointestinal disease Diabetes Asthma Pulmonary failure Renal failure Nasal fracture	Approval date	2021-09-21, 1400/06/30
Age	From 18 years old to 45 years old	Ethics committee reference number	IR.SBMU.MSP.REC.1400.403
Gender	Both	Health conditions studied	
Phase	2	1	
Groups that have been masked	No information	Description of health condition studied Rhinoplasty	
Sample size	Target sample size: 60 Actual sample size reached: 60	ICD-10 code ICD-10 code description	
Randomization (investigator's opinion)	Randomized	Primary outcomes	
Randomization description	Patients are randomly divided into two groups of dexamethasone or ketorolac with a ratio of 1:1. Block randomization will be performed via computer generated codes by using sealedenvelope website (www.sealedenvelope.com). Briefly, one of the researchers who is not involved in the treatment and assessment phases, prepares paired blocks (each block size=4) and 20 sequence lists, and put the assigned sequence in the same sealed envelopes. Then, according to randomization, the envelopes will be given to the therapist researcher.	1	
Blinding (investigator's opinion)	Not blinded	Description Severity of peri-ocular edema based on standard 4-grade scoring tool	
Blinding description		Timepoint 7 days after the operation	
Placebo	Not used	Method of measurement standard 4-grade scoring tool	
Assignment	Parallel	2	
Other design features		Description Severity of peri-ocular ecchymosis based on standard 4-grade scoring tool	
Secondary Ids	empty	Timepoint 7 days after the operation	
Ethics committees		Method of measurement standard 4-grade scoring tool	
1		Secondary outcomes empty	
Ethics committee		Intervention groups	
		1	
		Description In intervention group 1, patients will receive intravenous dexamethasone (8 mg, IRANHORMONE), one dose before and three doses every 8 hours after surgery	
		Category Treatment - Drugs	

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Description

Patients in interventional group 2, will receive one dose (30 mg) of Ketorolac (IRAN HORMONE) intramuscularly after induction of anesthesia and will receive two doses of 30 mg every 8 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Educational Hospital

Full name of responsible person

Dr. Bijan Nagibzadeh

Street address

Loqman Hakim Hospital, Kamali Street, Lashgar Crossroads

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

loghman.hospital@sbmu.ac.ir

Web page address

<https://lhmc.sbmu.ac.ir/index.jsp?pageid=18901&p=1>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway, Velenjak

City

Tehran

Province

Tehran

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1985717434

Phone

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zarghi@sbmu.ac.ir

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

Dr. Bijan Nagibzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Ear, Nose, and Throat

Street address

Loqman Hakim Hospital, Kamali Street, Lashgar Crossroads

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The clinical report and study protocol will be published in the form of a scientific article. However, no decision has been made yet regarding the IPD file and the analysis map. However, it can only be provided to individuals or related organizations in specific cases.

When the data will become available and for how long

The access period starts from 2022

To whom data/document is available

Academic researchers and health officials

Under which criteria data/document could be used

The IPD file and the study protocol can be used upon request by relevant organizations and health decision-makers in order to check its accuracy or to use it in the design of subsequent studies by mentioning the primary source.

From where data/document is obtainable

Ear Research Center of Loghman Hakim Hospital

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

A written request to the academic officer of the study

Comments