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

Public title
Effect of dexamethasone and ketorolac on edema and ecchymosis after rhinoplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-45 years Patients who are candidate for rhinoplasty
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
Age
From **18 years** old to **45 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Not 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 of Faculty of Medicine, Shahid Beheshti University of Medical Sciences, Tehran
Street address
Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1333635445
Approval date
2021-09-21, 1400/06/30
Ethics committee reference number
IR.SBMU.MSP.REC.1400.403

Health conditions studied

1

Description of health condition studied
Rhinoplasty
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Severity of peri-ocular edema based on standard 4-grade scoring tool
Timepoint
7 days after the operation
Method of measurement
standard 4-grade scoring tool

2

Description
Severity of peri-ocular ecchymosis based on standard 4-grade scoring tool
Timepoint
7 days after the operation
Method of measurement
standard 4-grade scoring tool

Secondary outcomes

empty

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

2

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
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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

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1985717434

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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

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr. Bijan Nagibzadeh

Position
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Person responsible for updating data

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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