Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The comparison of single dose preemptive intravenous ketorolac and paracetamol on postoperative pain after septorhinoplasty

Protocol summary

Study aim
The comparison of single-dose preoperative intravenous ketorolac and paracetamol on postoperative pain after septorhinoplasty

Design
Three-group clinical trial (2 intervention groups and 1 control group), with parallel groups, double-blind, randomized, phase 3 on 108 patients aged 18 to 50 years of class I and II ASA who are candidates for septorhinoplasty. The random sequence generation site (www.sealedenvelope.com) is used for randomization.

Settings and conduct
108 patients in Ghadir Hospital in Shiraz are studied in 3 groups (36 patients in each group) and postoperative pain is evaluated. In group 1: 40 mg intravenous ketorolac in 100cc of normal saline is injected 30 minutes before surgery. 2: 1000 mg of paracetamol in 100cc of normal saline is injected 30 minutes before the operation. Group 3 (control) 100 cc of normal intravenous saline is injected 30 minutes before the operation. In this study, the anesthesiologist (who prepares the drugs and delivers the drug to the operating room), as well as the patient, anesthesia resident, and recovery nurse Data analyzers, are blinded to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Obtaining informed consent Candidate patients for rhinoplasty with the age group of 18-50 years and class (ASA) I, II. Exclusion criteria: History of drug allergy to ketorolac and paracetamol History of long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) and narcotics

Intervention groups
In the intervention group,1: (n = 36) 40 mg of ketorolac is injected intravenously in 100cc of normal saline 30 minutes before the operation. In group 2: (n = 36), 1000 mg Paracetamol is injected in 100cc of normal saline 30 minutes before the operation, and in the control group (36 people) 100cc of normal saline is injected 30 minutes before the operation.

Main outcome variables
Postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180922041084N6**
Registration date: **2022-03-08, 1400/12/17**
Registration timing: **prospective**

Last update: **2022-03-08, 1400/12/17**
Update count: **0**

Registration date
2022-03-08, 1400/12/17

Registrant information

Name
Maryam Tabibzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-09, 1401/01/20

Expected recruitment end date
2022-05-31, 1401/03/10

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of single dose preemptive intravenous ketorolac and paracetamol on postoperative pain after septorhinoplasty

Public title

The comparison of single dose preemptive intravenous ketorolac and paracetamol on postoperative pain after septorhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Obtaining informed consent Candidate patients for rhinoplasty with age group of 18-50 years and class (ASA) I, II

Exclusion criteria:

History of drug allergy to ketorolac and paracetamol History of long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) and narcotics History of gastrointestinal bleeding, Stomach ulcers or inflammatory bowel disease Diabetes or neuropathic diseases

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, using the random blocking method, 108 patients are divided into 12 blocks with a size of 9 into three groups. Blocking will be determined using a random number table of random number generation software. Blocking and sequencing for concealment by a non-involved person in the study will be done by matched opaque envelopes. Paracetamol and a control group of normal saline will be given. Then, based on the obtained blocks and in the order of allocation, the drugs will be given to the patients. This study is a two-way blind.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medicines are prepared by an anesthesiologist who is not aware of how the study is performed and are delivered to the anesthesiologist in the operating room, who is also unaware of how the study is performed. Transferring the patient to the recovery room and handing over the patient to the recovery staff will not give them any information and thus the patient, anesthesia resident and recovery nurse, and the inpatient ward and data analyzer will be blinded to the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciencs

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2021-11-15, 1400/08/24

Ethics committee reference number

IR.SUMS.MED.REC.1400.603

Health conditions studied

1

Description of health condition studied

rhinoplasty surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post operative pain

Timepoint

At 1, 6, 12 and 24 hours after surgery

Method of measurement

VAS SCORE scoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: To the group receiving ketorolac (36 people) 40 mg of ketorolac (made by Raha company) is injected intravenously in 100cc of normal saline 30 minutes before the operation.
Category
Treatment - Surgery

2

Description
Intervention group: In the group receiving paracetamol (36 people) 1000 mg of paracetamolMade by Samen Company of Mashhad) in 100cc of normal saline is injected 30 minutes before the operation.
Category
Treatment - Surgery

3

Description
Control group: The control group (36 people) is injected with 100 cc of normal intravenous saline 30 minutes before the operation.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghadir Mother and Child Hospital
Full name of responsible person
ZAHRA MESKOOB SARAVI
Street address
Above the Quran Gate - Golshan Town - Ghadir Mother and Child Specialized and Sub-Specialized Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab memarpoor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Shirin Farrokhyani
Position
Anesthesiology resident/physician
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is against our policy

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

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available