

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of the effect of dexamethasone and ketorolac on pain control in elective foot surgery

Protocol summary

Study aim

This study aims to compare the effect of dexamethasone and ketorolac on pain control in elective foot surgery

Design

After the surgery, the patients were randomly split into two groups of 20 based on a table of random numbers. Patients in the first group received 8 mg of dexamethasone intravenously. Also, for the second group, 90 mg of ketorolac (Caspian Tamin Rasht Company) was infused in 1 liter of normal saline serum within 24 hours. While the patients were not aware of the type of medicine they were receiving (first type blindness). During 24 hours of patient monitoring, postoperative pain evaluation was initially performed at recovery time in 0, 2, 4, and 6 hours after the injection by an unaware intern and by VAS.

Settings and conduct

This study was a double-blind, randomized clinical trial. Out of a total of 53 patients who referred to Akhtar and Imam hospitals with ASA I and II class in the age group of 20 to 60 years, 40 candidates were selected and were divided into two groups.

Participants/Inclusion and exclusion criteria

Criteria for entering: being in the age group of 20 to 60 years and a candidate for orthopedic surgery of the lower limbs. Criteria for withdrawal: Pregnant and lactating women with impaired renal function or dialysis, heart disease, contraindications to opioid medications, hemorrhage, especially gastrointestinal hemorrhage, history of high blood pressure, history of anemia and thrombocytopenia, drug addiction, and asthma and lung disease and allergies to NSAID.

Intervention groups

dexamethasone and ketorolac Patients in the first group receive 8 mg of dexamethasone intravenously. Also, for the second group, 90 mg of ketorolac (Caspian Tamin Rasht Company) infused in 1 liter of normal saline serum within 24 hours.

Main outcome variables

pain control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190304042908N2**

Registration date: **2020-07-17, 1399/04/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-17, 1399/04/27**

Update count: **0**

Registration date

2020-07-17, 1399/04/27

Registrant information

Name

mahshid ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2588

Email address

ghasemimahshid529@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of dexamethasone and ketorolac on pain control in elective foot surgery

Public title
Comparison of the effect of dexamethasone and ketorolac on pain control in elective foot surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
People who are candidates for lower limb orthopedic surgery. Be in the age range of 20 to 60 years.
Exclusion criteria:
Women who are pregnant and breastfeeding People with impaired renal function or dialysis People with heart disease, use of warfarin during treatment, People with contraindications to opioid medications People with gastrointestinal hemorrhage, history of high blood pressure People with history of anemia and thrombocytopenia People with drug addiction People with asthma and lung disease and allergies to NSAID.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients included in the study were divided into 2 groups by a random-number table. The research sample was determined using sampling method based on entry criteria and considering the possibility of destruction, 40 people .People are selected with easy sampling and are enrolled in the study. Then, they are divided into two groups of control and intervention by simple random sampling law

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 Shahid Beheshti University of Medical Sciences
Street address
Velenjak st, Tehran
City
Tehran
Province
Tehran
Postal code
15683287
Approval date
2019-11-24, 1398/09/03
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.417

Health conditions studied

1

Description of health condition studied
Patients who have lower limb orthopedic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain rate

Timepoint
Before injection and 2, 4, and 6 hours after the injection

Method of measurement
Visual Analog Scale VAS Pain: This scale represents the pain of patients in general. This scale is plotted as a 10-cm line, and the pain range is between 0 and 10 cm. The zero number does not show any pain, the number 1 to 3 mild pain, the number 4 to 6 average pain and the number 7 to 10 severe pain. The internal stability of this tool is 0.85. Up to 95 /. ROM: The neck flexion rate is measured using a goniometer. In this way, the goniometer axis is placed in the neck of the neck of the neck and on the proximal shoulder. The fixed arm is held along the horizons and movable arm along the longitudinal line of the neck, and the neck flexion range is asked from the person to move the neck forward without moving the head, and the angular changes are recorded.

Secondary outcomes
empty

Intervention groups

1

Description

Intervention group1: received 8 mg of dexamethasone intravenously
Category
Treatment - Drugs

2

Description
Intervention group2: 90 mg of ketorolac (Caspian Tamin Rasht Company) was infused in 1 liter of normal saline serum within 24 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Mahshid Ghasemi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziaee
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
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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
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
Mahshid Ghasemi
Position
Assistance professor
Latest degree
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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

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable