Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the effectiveness of high and low dose Dexamethasone intravenous injection on the severity of postoperative pain, sleep quality in patients after total knee arthroplasty

Protocol summary

Study aim

Comparison the effectiveness of high and low dose Dexamethasone intravenous injection on the severity of postoperative pain, sleep quality in patients after total knee arthroplasty

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 90 patients. Permuted block randomization method with block size 6 was used for randomization.

Settings and conduct

The day before the surgery, by referring to the department of the Shahid Beheshti hospital of Babol samples will be selected and a questionnaire sleep quality and pain level questionnaire will be completed. Patients will be randomly divided into one of three groups A,B&C. This process will be done by the ward personnel and the day before each patient's operation, so the patient will not know about his treatment group. It should be noted that the personnel in the department do not have information about the allocation of patients in groups. The information related to the treatment groups is also not obvious to the biostatistician. On the day of surgery, the anesthesiologist will give 4 mg of Dexamethasone in the control group(A), 16 mg of Dexamethasone in the high-dose Dexamethasone group(B), and 8 mg of Dexamethasone in the low-dose Dexamethasone group(C). After the spinal anesthesia is off, the pain level of the patient is measured every four hours until 48 hours after the surgery based on VAS. The sleep quality questionnaire is completed again two weeks after surgery.

Participants/Inclusion and exclusion criteria

The entry criteria is over 18 years of age and the non-entry criteria is a history of diabetes.

Intervention groups

In the control group, 4 mg of intravenous Dexamethasone, in the high-dose Dexamethasone group, 16 mg of intravenous Dexamethasone, and in the low-dose Dexamethasone group, 8 mg of intravenous Dexamethasone will be given to the patients.

Main outcome variables

Pain level؛ Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230316057742N1**
Registration date: **2023-04-24, 1402/02/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-04-24, 1402/02/04**
Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name
majid khalilizad
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of high and low dose Dexamethasone intravenous injection on the severity of postoperative pain, sleep quality in patients after total knee arthroplasty

Public title

Effect of Dexamethasone on the severity of postoperative pain, sleep quality in patients after total knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age : 18 years and above

Exclusion criteria:

Any history of diabetes and taking antidiabetic medicines

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be selected by available sampling method and then will be randomly divided into one of three groups (A: 4mg Dexamethasone), (B: 8mg Dexamethasone) and (C: 16mg Dexamethasone). For random allocation, the method of permutated block randomization consisting of letters A, B and C is used in blocks of six. The process of random assignment will be such that first all six permutations of letters A, B and C (two of each letter) are written on separate sheets and thrown into a container. Randomly, we take out one of the sheets from the container and write down the composition written on it and return it to the container. According to the sample size in this study (90 people), this process is repeated and the extracted composition is recorded each time. Then, each letter is assigned a number from 1 to 90 in the order of the written letters, and each letter is placed in a separate envelope, and the number associated with the letter is noted on each envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient will not know about his treatment group. The researcher does not know the type of intervention allocated. It should be noted that the care personnel present in the department also do not have information about the allocation of patients in groups and the results of the intervention. The information related to the treatment groups is also not obvious to the biostatistician and the groups will be used only with the letters A, B and C for the analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Shahid Beheshti Hospital, Shahid Sargerd Ghasemi St , Babol

City

Babol

Province

Mazandaran

Postal code

4716681451

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.267

Health conditions studied

1

Description of health condition studied

Total knee arthroplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity score based on visual analogue scale, Sleep quality score based on Saint Mary's questionnaire

Timepoint

The sleep quality questionnaire is completed once the day before the operation and once again two weeks after

the surgery, The intensity of pain is measured once the day before the operation and then after the end of the spinal anesthesia every four hours until 48 hours after the surgery based on the Visual Analogue Scale.

Method of measurement

Sleep quality based on Saint Mary's questionnaire, Pain intensity based on Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Patients of this group receive a dose of 4 mg of intravenous dexamethasone during surgery

Category

Treatment - Drugs

2

Description

First Intervention group: Patients of this group receive a dose of 8 mg of intravenous dexamethasone during surgery

Category

Treatment - Drugs

3

Description

Second Intervention group:

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid beheshti hospital

Full name of responsible person

Majid Khalilizad

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Shahid Beheshti Hospital, Shahid Sargerd Ghasemi St, Babol

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Majid Khalilizad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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