Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of corticosteroid injection on respiratory indices and vital signs after cement use in knee replacement

Protocol summary

Study aim

To evaluate the effect of corticosteroid injection during cement implantation in preventing heart and respiratory accidents in patients undergoing arthroplasty.

Design

All patients undergoing knee replacement using convenience sampling, after obtaining written consent, are divided into two groups of intervention and control by block randomization. The sample size of this double-blind study will be 200 people, which will be 100 people in each group.

Settings and conduct

In this study, the surgeon will be aware of the type of intervention performed, but the analyst and patients will not be aware of the type of intervention. All patients with knee replacement referred to Hazrat Rasoul and Moheb Mehr hospitals for 4 months in 2021 are divided into two intervention and control groups. The patients in the intervention group will have a hydrocortisone injection during cement placement, which will not be done in the control group. The patients' data during and after surgery is recorded by the anesthesia technician and then by the nurse, who does not know the type of intervention. After the patient is discharged, the information from the file is recorded in the checklist by a person who knows the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age over 18 years, need for joint replacement, and willingness to participate in the study. A history of dementia or psychological disorders that affect decision-making power is the criterion for not including in the study.

Intervention groups

In patients in the intervention group, intravenous injection of 100 mg of hydrocortisone during cement implantation is used, which is not done in the control group.

Main outcome variables

Heart rate; Blood Pressure; Oxygen saturation; (pCO2) partial pressure of carbon dioxide؛ power of hydrogen(pH)؛ Bicarbonate (HCO3)؛ Base Excess (BE); Blood sugar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180528039883N3**
Registration date: **2021-08-09, 1400/05/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**
Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Ali Yeganeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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yeganeh471@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2021-08-16, 1400/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of corticosteroid injection on respiratory indices and vital signs after cement use in knee replacement

Public title

Evaluation of the effect of corticosteroid injection in knee replacement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Need for Arthroplasty Willingness to participate in the study

Exclusion criteria:

History of dementia or psychiatric and psychological disorders that affect decision-making power

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the participants in the study using inclusion and non-inclusion criteria, to prevent the occurrence of bias in the selection of participants to intervention and control groups, we will use the randomization method to minimize the opinion of researchers in selecting participant to study groups. The block randomization method was used in this study. The size of the blocks is considered to be four and will be selected randomly so that it is not predictable to the participants based on the blocks. First, we will receive using Random Allocation software and by determining the sample size, the number of groups, the type of randomization and is random the order of the blocks in the software output and will be shown in the software output of groups with letters A and B. Then, after selecting each patient based on the inclusion and non-inclusion criteria, the project manager will be informed and he will tell the type of intervention of that patient based on the order of inclusion of patients and compliance with the number mentioned in the randomization output.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, the surgeon will be aware of the type of intervention performed, but the analyst and patients will not be aware of the type of intervention. The information of all patients is reviewed and recorded in the file by the anesthesia technician during the surgery and after the surgery in the recovery room, and by the nurse after the transfer to the ward who is different depending on the work shift and does not know the type of intervention. Then, after the patient's discharge, the information is recorded in the checklist by a person who knows the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran 14496-14535, IRAN

City

Tehran

Province

Tehran

Postal code

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Approval date

2021-04-06, 1400/01/17

Ethics committee reference number

IR.IUMS.REC.1400.025

Health conditions studied

1

Description of health condition studied

Bone Cement Implantation Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Percentage of patients with high heart Rate

Timepoint

Before anesthesia, before implanting cement, immediately after implanting cement, and half an hour after implanting cement

Method of measurement

Heart Monitoring

2

Description
Percentage of patients with blood pressure drop
Timepoint
Before anesthesia, before implanting cement, immediately after implanting cement, and half an hour after implanting cement
Method of measurement
Sphygmomanometer

3

Description
Percentage of patients with oxygen saturation drop
Timepoint
Before anesthesia, before implanting cement, immediately after implanting cement, and half an hour after implanting cement
Method of measurement
Pulse Oxymeter

4

Description
pCO2
Timepoint
half an hour after implanting cement
Method of measurement
Arterial Blood Gas

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: One venous infusion of one 100 mg/2 ml ampoule of ABURAIHAN Co. hydrocortisone during the cement implantation
Category
Treatment - Drugs

2

Description
Control group: No venous injection of hydrocortisone during the cement implantation
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat e Rasoul Hospital
Full name of responsible person
Ali Yeganeh
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Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av, Tehran, 1449614535, IRAN
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person

Ali Yeganeh
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
It is possible to share some of the data related to the main outcomes and medical history of the study participants, but information that in any way identifies the study participants will not be available at all.
When the data will become available and for how long
Starting the access period after printing the results
To whom data/document is available
The data will only be made available to researchers at academic centers
Under which criteria data/document could be used
If people request further studies on the data, they can contact the project manager
From where data/document is obtainable
Applicants are required to contact the research project manager
What processes are involved for a request to access data/document
After reviewing the application and the academic environment, the applicant will be provided with the data.
Comments