

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of adding Corticosteroid to the periarticular injection cocktail for pain control after total hip and total knee arthroplasty

Protocol summary

Study aim

Evaluation of the effect of corticosteroid on pain in the periarticular injection after total knee and hip replacement .

Design

Clinical trial ,with parallel group, randomized into the two study groups using a simple numerical randomization table (even and odd)

Settings and conduct

Forty two cases of total hip arthroplasty (THA) and 42 cases of total knee arthroplasty (TKA) patients were included in the study. Each group subdivided randomly in group A (intervention group who receive cocktail with Corticosteroid) and group B (control group who receive cocktail without Corticosteroid). one day before surgery pain will be evaluated with visual analogue scale (VAS) and then again at four different time-points pain will be measured by VAS for both THA and TKA at 12, 24, 48, 72 hours after surgery. Knee range of motion (ROM) and straight leg raise (SLR) will be checked only for the TKA group. The study will be done in Shafayahyayian hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria :The patient need total knee or hip arthroplasty Exclusion criteria : Diabetes ,Immunosuppressive Disease,IV drug abuser

Intervention groups

Intervention group will include the patients that during their surgery(total hip or knee arthroplasty) will receive Corticosteroid in their periarticular injection cocktail. Control group will include the patients that during their surgery(total hip or knee arthroplasty) will receive cocktail without Corticosteroid in periarticular injection.

Main outcome variables

Pain: Straight leg raise: Range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161121031003N2**

Registration date: **2019-04-05, 1398/01/16**

Registration timing: **retrospective**

Last update: **2019-04-05, 1398/01/16**

Update count: **0**

Registration date

2019-04-05, 1398/01/16

Registrant information

Name

Kaveh Gharanizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2000

Email address

gharanizadeh.k@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-31, 1397/10/10

Expected recruitment end date

2019-03-30, 1398/01/10

Actual recruitment start date

2017-12-29, 1396/10/08

Actual recruitment end date

2018-09-21, 1397/06/30

Trial completion date

empty

Scientific title

The effect of adding Corticosteroid to the periarticular injection cocktail for pain control after total hip and total knee arthroplasty

Public title

The effect of Corticosteroid in reducing pain after joint replacement.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients who will undergo total knee or hip arthroplasty.

Exclusion criteria:

Diabetes Immunosuppressive disease IV drug abusers

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **84**

Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who are on the surgery room waiting list are randomly divided into two treatment groups for total knee arthroplasty and total hip arthroplasty. Patients in each group are assigned numbers between 1-42. After that, 21 numbers in each group are randomly selected by Excel and receive the injection with corticosteroid. The remaining numbers receive the injection without corticosteroid.

Blinding (investigator's opinion)

Single blinded

Blinding description

We explain the patients, we want to inject an analgesic cocktail around your hip and knee during the surgery but they don't know anything about the detail of combinations that will be used in their cocktail. The researcher who evaluates the post operative pain and other criteria will be blinded about the cocktail type were used for the patient.

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

Mojahedin Khalgh Street

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-12-25, 1397/10/04

Ethics committee reference number

IR.IUMS.FMD.REC.1397.124

Health conditions studied**1****Description of health condition studied**

The effect of corticostreoid in periarticular injection in total knee and hip arthroplasty

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Assess the pain

Timepoint

Preoperative, 12 h, 24h, 48 h, 72 hours after surgery

Method of measurement

Visual analogue scale

2**Description**

Straight leg raising

Timepoint

12 hours after total knee arthroplasty

Method of measurement

Ask the patient to raise the leg while the knee is extended.

3**Description**

Range of motion

Timepoint

5 days after surgery

Method of measurement

Using conveyor

Secondary outcomes

empty

Intervention groups

1

Description

Control group: include the patients that during their surgery(total hip or knee arthroplasty) will receive cocktail without corticosteroid in periarticular injection.

Category

Treatment - Drugs

2

Description

Intervention group: include the patients that during their surgery(total hip or knee arthroplasty) will receive corticosteroid (40 mg depomedrol Pfizer) in their periarticular injection cocktail.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyayian hospital

Full name of responsible person

Abolfazl Bagherifard

Street address

Mojahedin Eslam ,Baharestan square

City

Tehran

Province

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Postal code

1449614535

Phone

+98 21 3354 2005

Email

gharanizadeh.k@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Kaveh Gharanizadeh

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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

Kaveh Gharanizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Not applicable

Title and more details about the data/document

VAS score ,range of motion ,straight leg raise in each patient published in SPSS program

When the data will become available and for how long

After collecting all data

To whom data/document is available

For all of the people

Under which criteria data/document could be used

No special condition

From where data/document is obtainable

Shafa Yahyayian hospital library .Mojahedin eslam street ,Baharestan square, Email :
khorrami.am@gmail.com Email
:gharanizadeh.k@iums.ac.ir

What processes are involved for a request to access data/document

Email to mentioned address .In the library of Shafayahyayian hospital ,thesis of Dr.Amir Mohsen Khorrami

Comments