Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 ,Immunosuppersive 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)

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+98 21 3354 2000

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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 Immunosuppresive 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 arthroplasry . Patients in each group are assigned numbers between 1-42. After that ,21 numbers in each group are randomly selected by Ecxel 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 Ẏahyayian hospital
Full name of responsible person
Abolfazl Bagherifard
Street address
Mojahedin Eslam ,Baharestan square
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Tehran
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Sponsors / Funding sources

1

Sponsor
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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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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 libraray .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 libarary of Shafayahyayian hospital ,thesis of Dr.Amir Mohsen Khorrami

Comments