Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Preoperative effects of single high dose prednisolone in patients with total hip arthroplasty

Protocol summary

Study aim
Evaluation of single high dose prednisolone preoperative side effects in patients with total hip arthroplasty

Design
This study is a Double blind RCT Patients are randomly assigned to one of two groups. Demographic characteristics of patients participating in this study are obtained from the information in patients' files and also demographic characteristics of patients participating in this study are obtained from the information obtained from the designed questionnaires.

Settings and conduct
Patients referred to Sina Hospital who are over 18 years old and need total hip arthroplasty.

Participants/Inclusion and exclusion criteria
All patients over 18 years of age who are candidates for total hip arthroplasty surgery except Multiple trauma patients with fractures in different areas, patients who are candidates for standard surgery. Patients with a history of renal, hepatic, gastric ulcer, pregnancy, lactating women, history of corticosteroids, patients under 18 years of age, patients taking corticosteroids or opioids, diabetic neuropathy and patients with heart failure, patients with poor control Diabetes mellitus (Poor control DM) As well as patients with poor blood pressure control (Poor control high blood pressure) They are excluded from the study.

Intervention groups
Intervention group: Patients who have undergone primary hip replacement. Control group: There are patients who undergo total hip replacement arthroplasty without knowing it.

Main outcome variables
Quality of sleep Setup time the pain Duration of hospitalization

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200118046174N3**
Registration date: **2021-03-01, 1399/12/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-01, 1399/12/11**
Update count: **0**

Registration date
2021-03-01, 1399/12/11

Registrant information

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Hossein Shafiei

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-10, 1399/06/20

Expected recruitment end date
2021-11-11, 1400/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preoperative effects of single high dose prednisolone in patients with total hip arthroplasty

Public title

The effect of prednisolone in patients with total hip arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients who are candidate for primary hip arthroplasty all the patients with avascular necrosis of femoral head all the patients with femoral neck fracture who are candidate for primary hip arthroplasty all the patients with severe hip joint osteoarthritis who are candidate for primary hip arthroplasty

Exclusion criteria:

Multiple trauma patients with fractures in different areas, Patients who are not candidates for standard surgery. Patients with a history of renal failure, liver, gastric ulcer, pregnancy, lactating women, history of corticosteroids Patients under 18 years of age, patients taking corticosteroids or opioids, patients with diabetic neuropathy and patients with heart failure, patients with poor control of diabetes mellitus (Poor control DM) Also, patients with poor control of high blood pressure are excluded from the study.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

randomization was done by "round list" software and with this software,patients will placed into control group or treatment group. Patients are randomly assigned to one of two groups,patient and doctor are not aware of patient selection that means neither doctor nor patients do not know about which patient will enter to study . Half of the patients are treated with methylprednisolone and the other half are treated with placebo. Patients in the methylprednisolone-treated group will receive IV 125 mg of methylprednisolone on the morning of surgery and patients in the control group receive 2 cc of isotonic saline injection. Patient anesthesia is total or general according to the anesthesiologist.

Blinding (investigator's opinion)

Double blinded

Blinding description

for elimination of bias secendary to doctor or patients and result evaluator knowe, the type of treatment and its probable effect on the study result , the study done as double blind. according to that fact, the placebo and methylprednisolone are in same shaped box and are seald it is predictable that doctor and patient dont know which patient receive which type of drug. It is from both the doctor and the patient Patients are operated on by 4 assistants in year 3. Standard surgery is performed for all patients and before surgery 1 gr acetaminophen is injected for all patients and after surgery 1 gr acetaminophen is injected as BD and Pregabalin 75 mg as QHS for pain control. All patients receive prophylactic AB before surgery, and all patients receive cephalexin 500 mg TDS oral antibiotic for 7 days after surgery. After surgery for low molecular weight patients, heparin is injected for prophylaxis for 2 to 4 weeks for DVT prophylaxis. After 24-48 hours of surgery, if the general condition is good and proper, patients are discharged from the hospital and are visited at the clinic at intervals of 2 weeks, 6 weeks, 12 weeks and 24 weeks. In all patient visits, X-rays are performed in 2 directions and the graphs are checked by the senior orthopedic assistant in the direction of union. Patients are also examined at all times by an orthopedic assistant for R / O infection. The definition of union in radiography is the establishment of cortical continuity between two parts and the absence of pain is clinical. Multiple trauma patients with fractures in different areas, patients who are candidates for standard surgery. Patients with a history of renal, hepatic, gastric ulcer, pregnancy, lactating women, history of corticosteroids, patients under 18 years of age, patients taking corticosteroids or opioids, diabetic neuropathy and patients with heart failure, patients with poor control Diabetes mellitus (Poor control DM) As well as patients with poor blood pressure control (Poor control high blood pressure) They are excluded from the study. All diabetic patients admitted to the study undergo endocrine counseling to control blood sugar before and after surgery. In the text of the informed consent, the complications and benefits of entering the plan, and the methods of controlling possible complications, will be explained in a clear and understandable manner. The current standard procedure for patients undergoing arthroplasty is early initiation of the patient After surgery and the use of analgesics with intravenous acetaminophen to reduce pain, The use of physiotherapy is the currency of the operation to strengthen the abductors.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address
emam khomeni
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۱۱۳۶۷۴۶۹۱۱
Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1399.040

2

Ethics committee
Name of ethics committee
Ethics committee of tehran University of Medical Sciences
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Approval date
2020-06-28, 1399/04/08
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1399.040

Health conditions studied

1

Description of health condition studied
The effect of prednisolone on hip joint fractures leading to total hip arthroplasty
ICD-10 code
M87.0
ICD-10 code description
Idiopathic aseptic necrosis of bone

Primary outcomes

1

Description
Patients after surgery underwent pain intensity assessment with a score of one to ten,Sleep quality assessments are completed by completing a psqi questionnaire, commissioning assessment, length of stay, and other demographic findings.
Timepoint
At intervals of 2 weeks, 6 weeks, 12 weeks and 24 weeks
Method of measurement
In all patient visits, X-rays are performed in 2 directions and the graphs are checked by the senior orthopedic assistant. Patients are also examined at all times by an orthopedic assistant for R / O infection

Secondary outcomes

empty

Intervention groups

1

Description
the intervention group will receive 125mg intravenous methylprednisolone acetate as an anti-inflammatory agent 12 hours before surgery as a single dose. methylprednisolone is a moderately active glucocorticoid. there is high glucocorticoid activity with this drug (5times more than hydrocortisone) with no mineralocorticoid action. this is mostly be used as an immune suppressive and anti-inflammatory drug. liver metabolise this drug to sulfate and inactive glucocorticoid. inactive metabolites and some amounts of non-metabolised drug will have renal excretion. very low amounts of the drug will have fecal excretion. biological half life of the grug is 18 to 36 hours.
Category
Treatment - Drugs

2

Description
Control group: "Placebo recipients in the form of 2 cc intravenous normal saline serum is completely similar to the intervention group and single dose at the same time of hospitalization at the same time with the intervention group.Normal saline is a group of crystalloid solutions containing electrolytes in the form of 500 or 1000 cc serum. It is an electrolyte serum and contains sodium and chlorine.Nine grams per liter or 308 mOsm / L.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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Grant name
Ranking of research projects
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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