

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

Name

Hossein Shafiei

Name of organization / entity

Country

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 be 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 secondary to doctor or patients and result evaluator knowing the type of treatment and its probable effect on the study result, the study was done as double blind. according to that fact, the placebo and methylprednisolone are in same shaped box and are

sealed it is predictable that doctor and patient don't know which patient receives 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

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emam khomeni
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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 drug 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
Sina hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Masoud Ghasemi

Position

resident

Latest degree

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Other areas of specialty/work

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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