

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of interavenous patient controlled analgesia and epidural patient controlled analgesia methods after knee or hip arthroplasty operations in Ayatollah Kashani hospital -Isfahan

Protocol summary

Summary

This study will be done in order to compare two methods of patient controlled analgesia after knee or hip arthroplasty on patients referred to Isfahan Kashani Hospital. Patients who sign the informed consent form of the research will be randomly assigned to two groups in the surgery room (considering the equal number of each type of surgery in two groups). The patients in group A (epidural patient controlled analgesia)and group B (venous patient controlled analgesia). In all patients, epidural anesthesia catheter will be connected to P.C.A pump remaining for 24 hours and venous catheter pump will be installed too. In group A, mixture of Fentanil and marcaiene solution will be prescribed by P.C.A pump as intervention and in group B morphine via venous P.C.A pump as a control method. The prescription of medicine and placebo continues up to 24 hours and patients will be under observation in I.C.U. In addition, 150 CC normal saline will be prescribed as placebo by venous pump in group A and by epidural pump in group B. An independent assessor will check the level of consciousness, blood pressure, heart rate, respiratory rate, level of pain, and side effects such as nausea and vomiting, pruritus, urinary retention and additional narcotic usage based on predetermined times. The results will be compared between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902023771N1**

Registration date: **2010-06-15, 1389/03/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-06-15, 1389/03/25

Registrant information

Name

Gholamreza Khalili

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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khalili@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellory for Research & Technology, Isfahan University of Medical Sciences

Expected recruitment start date

2010-06-24, 1389/04/03

Expected recruitment end date

2011-04-21, 1390/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of interavenous patient controlled analgesia and epidural patient controlled analgesia methods after knee or hip arthroplasty operations in Ayatollah Kashani hospital -Isfahan

Public title

Patient Controlled Analgesia for Total Hip or Knee

Arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria of the study :patients that are in the range of 40-80 years ,have 1-3 ASA ,are candidates of hip or knee replacement surgery & sign the consent form. Non inclusion criteria:patients that have contraindication for regional anesthesia or coagulopathy ,platelet count less than 100000 or chronic renal failure (G.F.R<60),and narcotic addiction . Exclusion criteria : Incomplete regional anesthesia, change to spinal anesthesia.

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Regional ethics committee of Isfahan University of Medical Sciences

Street address

Vice Chancellory for Research & Technology, Bldg.no 4, Isfahan University of Medical Sciences, HezarJerib street

City

Isfahan

Postal code

81745-319

Approval date

2010-04-05, 1389/01/16

Ethics committee reference number

188147

Health conditions studied

1

Description of health condition studied

post hip or knee arthroplasty surgery pain

ICD-10 code

Z45.1

ICD-10 code description

Adjustment and management of infusion pump

Primary outcomes

1

Description

postoperative pain

Timepoint

0, 6, 12, and 24 hours after operation

Method of measurement

Visual analogue Scale

2

Description

Level of Conciousness

Timepoint

0, 6, 12, and 24 hours after operation after recovery room entrance

Method of measurement

A 4 point likert scale

3

Description

pulse rate

Timepoint

0, 6, 12, and 24 hours after operation

Method of measurement

pulse oximeter

4

Description

blood pressure

Timepoint

0, 6, 12, and 24 hours after operation

Method of measurement

oscillometer

5

Description

hypoxia

Timepoint

postoperative within 24 hours of surgery

Method of measurement

pulse oximeter

Secondary outcomes

1

Description

urinary retention

Timepoint

postoperative within 24 hours of surgery

Method of measurement

using checklist

2

Description

pruritus

Timepoint

postoperative within 24 hours of surgery

Method of measurement

using checklist

3

Description

vomitting and Nausea

Timepoint

postoperative within 24 hours of surgery

Method of measurement

using checklist

Intervention groups

1

Description

Intervention group: Epidural PCA(Analgesic Solution (marcaine 0.0625 -0.125% -fentanil 5ug/ml), continuous Rate (ml/hr): 4-10-Demand Dose (ml): 3-4-Lokout Interval: 10-15min) for 24 hours)+ 150 cc normal saline via Intravenous PCA pump as placebo

Category

Treatment - Devices

2

Description

Control group: Intravenous PCA (Morphine 1mg/ml-Size of bolus: 0.5-2.5mg- Lockout Interval (min): 5-10min- Continuous Infusion: 0.01-0.3mg/kg/hr) for 24 hours)+ 150 cc normal saline via Epidural PCA pump as placebo

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah kashani hospital

Full name of responsible person

Dr. Gholamreza Khalili

Street address

Ayatollah kashani hospital, Ayatollah kashani street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research & Technology, Isfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research & Technology

Street address

Vice Chancellory for Research & Technology, Bldg.No.4, Isfahan University of Medical Sciences, HezarJerib Street

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Isfahan

Grant name

گزارت پژوهشی

Grant code / Reference number

188147

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research & Technology, Isfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mahtab AghaKarimi

Position

Nurse/Master of Science

Other areas of specialty/work

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Position

Anesthesiologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty