

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of femoral block versus intravenous infusion pump on postoperative pain in patients underwent surgical repair of anterior cruciate ligament: a randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of femoral block versus intravenous infusion pump on postoperative pain in patients underwent surgical repair of anterior cruciate ligament. **Design:** A randomized clinical trial. **Setting and conduct:** All eligible patients with rupture of anterior cruciate ligament who will refer to the Beasat Hospital during the study period will be enrolled in to the trial. **Inclusion criteria:** (a) rupture of anterior cruciate ligament; (b) age of 12 to 70 years. **Exclusion criteria:** (a) sensitivity to local anesthesia; (b) unable to use infusion pump; (c) history of narcotic addiction; (d) chronic liver failure; (e) renal failure; (f) indication of repairing bilateral anterior cruciate ligament; (g) history of previous inguinal surgery; (h) tumor or enlarged inguinal lymph node; (i) femoral nerve neuropathy; (j) infection of the inguinal area. **Intervention:** Femoral block at the inguinal area using Marcaine 25% 10 ml single dose at the end of surgery. **Control:** Intravenous infusion pump using morphine 30 mg in 100 ml normal saline with the speed of 4 ml/min single dose at the end of surgery. **Primary outcome:** Pain at the surgical site at zero time and then every 4 hours for 24 hours after surgery using VAS. **Secondary outcome:** (a) patient's satisfaction at zero time and at 12 and 24 hours after surgery using Likert scale; (b) nausea and vomiting at zero time and then every 4 hours for 24 hours after surgery by question.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402279014N27**

Registration date: **2014-03-09, 1392/12/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-09, 1392/12/18

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan
University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2014-03-11, 1392/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of femoral block versus intravenous infusion pump on postoperative pain in patients underwent surgical repair of anterior cruciate ligament: a randomized clinical trial

Public title

Effect of femoral block versus intravenous infusion pump on postoperative pain in patients underwent surgical repair of anterior cruciate ligament

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: (a) rupture of anterior cruciate ligament; (b) age of 12 to 70 years. Exclusion criteria: (a) sensitivity to local anesthesia; (b) unable to use infusion pump; (c) history of narcotic addiction; (d) chronic liver failure; (e) renal failure; (f) indication of repairing bilateral anterior cruciate ligament; (g) history of previous inguinal surgery; (h) tumor or enlarged inguinal lymph node; (i) femoral nerve neuropathy; (j) infection of the inguinal area.

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to intervention and control group using tossing coin.
Blinding: Since the intravenous infusion pump is out of the body and will be seen by both patients and the physician, hence, the study cannot be blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethic Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Postal code

6517838695

Approval date

2014-01-20, 1392/10/30

Ethics committee reference number

D/P/16/35/9/3565

Health conditions studied

1

Description of health condition studied

Pain at surgical site at inguinal area

ICD-10 code

R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

Primary outcomes

1

Description

Pain at the surgical site

Timepoint

at zero time and then every 4 hours for 24 hours after surgery

Method of measurement

using VAS scale

Secondary outcomes

1

Description

patient's satisfaction

Timepoint

at zero time and at 12 and 24 hours after surgery

Method of measurement

using Likert scale

2

Description

nausea and vomiting

Timepoint

at zero time and then every 4 hours for 24 hours after surgery

Method of measurement

by question

Intervention groups

1

Description

Femoral block at the inguinal area using Marcaine 25% 10 ml single dose at the end of surgery.

Category

Treatment - Drugs

2

Description

Intravenous infusion pump using morphine 30 mg in 100 ml normal saline with the speed of 4 ml/min single dose at the end of surgery.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Hospital

Full name of responsible person

Dr Navid Hadadzadegan

Street address

Beasat Hospital, Shahed Square

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research the Technology,
Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-chancellor for Research the Technology, Hamadan
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

Beasat Hospital

Full name of responsible person

Dr Navid Hadadzadegan

Position

Resident of Anesthesiology

Other areas of specialty/work

Street address

Beasat Hospital, Shahed Square

City

Hamadan

Postal code

Phone

00

Fax

Email

hadadzadegan1359@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Beasat Hospital

Full name of responsible person

Dr Poursan Hajian

Position

Anesthesiologist

Other areas of specialty/work

Street address

Beasat Hospital, Shahed Square

City

Hamadan

Postal code

Phone

+98 81 1341 6392

Fax

Email

hajian@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

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