

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of local infiltration analgesia and epidural analgesia in postoperative pain management, functional outcomes and blood loss control in total knee arthroplasty : A randomized clinical trial

Protocol summary

Study aim

The goal of this randomized clinical trial is to evaluate the efficacy of LIA in patient who received spinal anesthesia in comparison with epidural analgesia combined with pain control infusion pump.

Design

Computer generated permutation digit method

Settings and conduct

Taleghani Hospital

Participants/Inclusion and exclusion criteria

TKA revision Bilateral TKA Collagen vascular disease
Neurovascular disease Hematologic disease
Coagulopathy Inclusion : 50 - 85 years old with knee pain
Don't response to conservative treatment

Intervention groups

Inter articular (knee) injection Pain pump

Main outcome variables

ROM Bleeding SLR Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170807035554N1**

Registration date: **2018-06-27, 1397/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-27, 1397/04/06**

Update count: **0**

Registration date

2018-06-27, 1397/04/06

Registrant information

Name

arash sajadi

Name of organization / entity

shaheed beheshti university of medicalscience

Country

Iran (Islamic Republic of)

Phone

+98 912 337 7215

Email address

arashsajadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-26, 1397/04/05

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of local infiltration analgesia and epidural analgesia in postoperative pain management, functional outcomes and blood loss control in total knee arthroplasty : A randomized clinical trial

Public title

Comparison of local infiltration analgesia and epidural analgesia in postoperative pain management, functional outcomes and blood loss control in total knee arthroplasty

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

50 - 85 years old with knee pain Don't response to conservative treatment

Exclusion criteria:
 TKA revision Bilateral TKA Collagen vascular disease
 Neurovascular disease Hematologic disease
 Coagulopathy

Age
 From **50 years** old to **85 years** old

Gender
 Both

Phase
 3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Computer generated permutation digit method

Blinding (investigator's opinion)
 Double blinded

Blinding description
 No information of who get treatment for health care & patients.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of
 Medical Sciences

Street address

Yaman st

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-05-16, 1397/02/26

Ethics committee reference number

IR.SBMU.MSP.REC.1397.260

Health conditions studied

1

Description of health condition studied

Osteoarthritis of Knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of Knee

Primary outcomes

1

Description

ROM Bleeding SLR Pain

Timepoint

2 Days & 2 Weeks

Method of measurement

A questionnaire based on VAS-Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Local Infiltration Analgesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Arash sajadi

Street address

Yaman st

City

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Email

arashsajadi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Arash sajadi

Street address
Yaman st
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 21 2243 2560
Email
arashsajadi@sbmu.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash sajadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Yaman st
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 23 0311
Email
arashsajadi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash sajadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Yaman st
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
+98 23 0311
Email
arashsajadi@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Arash Sajad
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Yaman st
City
Tehran
Province
Tehran
Postal code
1985711151
Phone
arashsajadi@sbmu.ac.ir
Email
arashsajadi@sbmu.ac.ir

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