Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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