Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparing the effect of of Remifentanil and Apotel on postoperative pain in Total knee arthroplasty patients (a clinical trial study)

Protocol summary

Study aim
Comparing the effects of remifentanil and Apotel in controlling postoperative pain in patients who are candidates for knee joint replacement

Design
Clinical trial with two parallel groups, double-blind, randomized, phase 2-3 on 62 patients, and with block randomization.

Settings and conduct
This study is conducted by collecting information and registering in the questionnaire from the participants of the study in both groups, which are randomized in a double blind and block format.

Participants/Inclusion and exclusion criteria
inclusion criteria: All candidate patients for knee joint replacement surgery referred to Amir-al-Momenin Hospital in Arak- Patients in the age range of 18 to 60 years- All patients undergo knee joint replacement by arthroplasty method- Patients have informed consent Exclusion criteria: All patients whose duration of surgery is more than 150 minutes- All patients in whom spinal anesthesia fails and have to undergo general anesthesia- Patients with ASA class 3 and 4- sensitivity/allergy to local anesthetics, Apotel and opioids- The patient has an underlying heart, lung, liver, kidney, etc. disease.

Intervention groups
For the patients of each group, Apotel or Remifentanil was injected after the surgery, and after the operation, Apotel or Remifentanil was added to the same combination of ondansetron, dexamethasone and morphine in the pain pump of each group.

Main outcome variables
Average post-operational pain by Visual Analogue Scale; average duration of postoperative analgesia; average postoperative opioid consumption

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220812055663N1**
Registration date: **2022-11-14, 1401/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-14, 1401/08/23**
Update count: **0**

Registration date
2022-11-14, 1401/08/23

Registrant information
Name
Seyed Ali Golrokh Moghadam
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 86 3278 5669
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gmoghaddam_ali@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01

Expected recruitment end date
2023-06-21, 1402/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of of Remifentanil and Apotel on postoperative pain in Total knee arthroplasty patients (a clinical trial study)

Public title
Comparing the effect of of Remifentanil and Apotel on postoperative pain in Total knee arthroplasty patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All candidate patients for knee joint replacement surgery referred to Amir-al-Momenin Hospital in Arak Patients in the age range of 18 to 60 years All patients undergo knee joint replacement by arthroplasty method Patients have informed consent
Exclusion criteria:
All patients whose duration of surgery is more than 150 minutes All patients in whom spinal anesthesia fails and have to undergo general anesthesia Patients with ASA class 3 and 4 sensitivity/allergy to local anesthetics, Apotel and opioids The patient has an underlying heart, lung, liver, kidney, etc. disease
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
All knee joint replacement candidates, referred to Amir-al-Momenin Arak Hospital, who meet the inclusion criteria for the study, will be divided as a randomized block design by the in charge anesthesiologist; in the form of quadruple blocks: ABB, ABAB, BABA, ABBA, BAAB, BBAA; into two groups of Remifentanil and Apotel.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to comply with Blindness, after obtaining informed consent from patients who are candidates for knee joint replacement, they are divided into two groups with equal numbers: A (Apotel) and B (Remifentanil). In group A (Apotel), 1 gram of Apotel in 100 cc of normal saline is placed on the infusion pump (syringe pump) by the anesthesiologist in charge of the plan to be infused within one hour after the surgery, and in group R (remifentanil) in which patients receive 0.5 gr/kg/min remifentanil in 100cc of normal saline infusion on a syringe pump to be infused within one hour during the surgery and blindness is also observed. None of the patients are aware of their placement in the study group, nor is the intern who is responsible for filling out the plan's questionnaire.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij Sq., Sardasht
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2022-07-05, 1401/04/14
Ethics committee reference number
IR.ARAKMU.REC.1401.083

Health conditions studied

1

Description of health condition studied
Knee joint arthritis
ICD-10 code
M25.5
ICD-10 code description
Pain in joint

Primary outcomes

1

Description
Average post-operational Visual Analogue Scale(VAS) in patients
Timepoint
2, 4, 8,12 and 24 hours after surgery
Method of measurement
Questionnaire

2

Description
Average duration of postoperative analgesia
Timepoint
Up to 24 hours after the operation
Method of measurement
Questionnaire

3

Description
Average opioid consumption after surgery
Timepoint
24 hours after the operation
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Average mean arterial pressure of patients in recovery
Timepoint
Duration of observation in recovery
Method of measurement
Monitor

2

Description
Average pulse rate of patients in recovery
Timepoint
Duration of observation in recovery
Method of measurement
Monitor

3

Description
Average SPO2 of patients in recovery
Timepoint
Duration of observation in recovery
Method of measurement
Monitor

Intervention groups

1

Description
Intervention group: Group A (Apotel): For patients in this group, after spinal anesthesia and hemodynamic stability of the patient and the start of surgery, 1 gram of Apotel is poured into 200cc of normal saline and it is infused for the patient within one hour of the beginning of surgery. After the end of the surgery and ensuring stable hemodynamics and confirmation of anesthesiologist, the patient is transferred to the recovery room and the pain pump is prepared by the in charge anesthesiologist at a speed of 8cc/hr until 12 hours after the surgery. 16 mg of dexamethasone, 8 mg of ondansetron and 10 mg of morphine will be poured inside the pain pump and its volume will be increased to 100 cc by normal saline and 2 grams of Apotel will be added to this solution.
Category
Treatment - Drugs

2

Description
Intervention group: In group R (remifentanil), after performing spinal anesthesia and ensuring hemodynamic stability and confirming anesthesia, and after the start of surgery, 0.5µ⁄(kg/min) of remifentanil will be infused within one hour of the beginning of surgery. At the end of surgery and ensuring stable hemodynamics and confirmation of anesthesiologist, the patient will be transferred to the recovery room and the pain pump will be prepared by the in charge anesthesiologist at a speed of 8cc/h until 12 hours after surgery. In both groups, 16 mg of dexamethasone and 8 mg of ondansetron, 10 mg of morphine will be placed inside the pain pump, and its volume will be increased to 100 cc by normal saline. In addition to the basic composition of the pain pump that was mentioned, 2 mg of remifentanil equivalent to 1 vial will be placed inside the pain pump under the supervision of an anesthetist.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al Mo'menin Hospital
Full name of responsible person
Seyed Ali Golrokh Moghadam
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2

Recruitment center
Name of recruitment center
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3

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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salehi58@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Seyed Ali Golrokh Moghadam
Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Medical Intern

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General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All clinical trial information, including participant data, study protocol, statistical analysis map, informed consent clinical study report, etc., can be shared after de-identifying participants.

When the data will become available and for how long
6 months after the results are published

To whom data/document is available
Study data will be publicly accessible.

Under which criteria data/document could be used
Documentation can be used for retrospective research or review article if publishing rights are preserved and the source is cited.

From where data/document is obtainable
By sending an email to gmoghaddam_ali@arakmu.ac.ir

What processes are involved for a request to access data/document
The aforementioned request will be reviewed by the authorities and concessionaires of this trial within a maximum period of one week.

Comments