

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Aug 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 Moghaddam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3278 5669

Email address

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 (remifentanyl), after performing spinal anesthesia and ensuring hemodynamic stability and confirming anesthesia, and after the start of surgery, 0.5µ (kg/min) of remifentanyl 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 remifentanyl 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

Street address

Basij (Sardasht) Sq, Next to the medical faculty

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2

Recruitment center

Name of recruitment center

Vali-ye-Asr Hospital

Full name of responsible person

Seyed Ali Golrokh Moghadam

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Valiye Asr Sq, Imam Khomeini St,

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3

Recruitment center

Name of recruitment center

Qods Hospital

Full name of responsible person

Seyed Ali Golrokh Moghadam

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Qods Hospital, Felestin St,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mehdi Salehi

Street address

Arak university of medical sciences, Basij Sq,
Sardasht

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Email

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

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Position

Medical Intern

Latest degree

A Level or less

Other areas of specialty/work

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