

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation the effect of intrathecal injection on the incidence and severity of pruritus in opium use disorder patients undergoing lower limbs orthopedic surgery

Protocol summary

Study aim

Comparison of the rate of pruritus in intrathecal fentanyl injection in opium-addicted patients in lower limb orthopedic surgeries.

Design

Clinical trial with parallel groups, double-blind, randomized

Settings and conduct

This study will be conducted on 68 opium-addicted patients who are candidates for elective orthopedic surgeries of the lower limbs under spinal Anesthesia. In the operating room, an anesthesiologist who knows the type of injected substance will enter the subarachnoid space with a 25 and 26 size Quincke spinal needle in a sitting position and at the level of L3-L4 or L4-L5. Then, in the FA groups, 2 ml of 0.5% Marcaine will be injected along with 1 ml of fentanyl, and in the MA group, only 3 ml of Marcaine will be injected.

Participants/Inclusion and exclusion criteria

Participants: patients candidates for elective orthopedic surgeries of the lower limbs under spinal anesthesia, entry conditions: people addicted to opium 20-55 years old, anesthesia status in class I and II classification of the American Society of Anesthesiology (ASA), signing an informed consent form, people using Drug addicts who are only addicted to opium. non-entry Conditions for not entering: presence of neurological disorders, presence of coagulation problem, presence of local skin infection at the injection site, presence of high cerebrospinal fluid pressure, presence of sensitivity to local anesthetics, use of corticosteroids in one year. Recent use of antihistamines in the last 8 weeks, history of food and drug allergies, people who use other drugs besides opium.

Intervention groups

The first intervention group: a group of addicted people who will receive intrathecal Marcaine together with

fentanyl for spinal anesthesia. The second intervention group: a group of addicted people who will receive only intrathecal Marcaine.

Main outcome variables

prevalence and intensity itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231223060498N1**

Registration date: **2024-02-07, 1402/11/18**

Registration timing: **prospective**

Last update: **2024-02-07, 1402/11/18**

Update count: **0**

Registration date

2024-02-07, 1402/11/18

Registrant information

Name

mansour deylami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3115 3367

Email address

mansour.deylami@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-03-24, 1403/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of intrathecal injection on the incidence and severity of pruritus in opium use disorder patients undergoing lower limbs orthopedic surgery

Public title

Investigating the effect of intraspinal narcotic injection on the occurrence of pruritus in patients with opium abuse disorder undergoing orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People addicted to opium, 20-55 years old Anesthesia status in class I and II classification of the American Society of Anesthesiology (ASA) Sign the informed consent form Drug users who are only addicted to opium

Exclusion criteria:

Presence of neurological disorders Coagulation problem Presence of local skin infection at the injection site High pressure of cerebrospinal fluid Presence of sensitivity to local anesthetics Cortone use in the last year Taking antihistamine in the last 8 weeks History of food and drug allergy People who use other drugs besides opium

AgeFrom **20 years** old to **55 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **68****Randomization (investigator's opinion)**

Randomized

Randomization description

The people participating in the study will be assigned to two intervention (FA) and control (MA) groups using the block randomization method. In this way, by using a dice that has 6 faces, the samples are assigned to their groups, a number is written on each face, and each number is assigned to one of the blocks in the table, which has its own state. it shows. Group A (Marcaine) and B (fentanyl and Marcaine). The complete list of randomized blocks will be provided to the principal investigator by the study epidemiology consultant.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding in this study is double blinding. So that both the patient does not know which treatment group he is in and the itch evaluator (Investigator) will not be aware of

the patient's treatment group type.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research ethics committee of Golestan University of Medical Sciences

Street address

Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

City

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Golestan

Postal code

4934174515

Approval date

2023-10-17, 1402/07/25

Ethics committee reference number

IR.GOUMS.REC.1402.398

Health conditions studied**1****Description of health condition studied**

Patients for elective lower limb fracture surgery(Superficial injury of knee and lower leg)

ICD-10 code

S80-S89

ICD-10 code description

Superficial injury of knee and lower leg

2**Description of health condition studied**

Patients for elective lower limb fracture surgery(Injuries to the ankle and foot)

ICD-10 code

S90-S99

ICD-10 code description

Injuries to the ankle and foot

Primary outcomes**1****Description**

prevalence and intensity itching

Timepoint

prevalence and intensity itching during surgery and recovery

Method of measurement

The severity of itching will be determined based on the extent of the itching area. In this way, itching in one area of the body will be considered mild, itching in two different areas of the body as moderate, and itching in 3 or more separate areas (generalized itching) will consider as severe.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: A group of addicts who will receive intrathecal Marcaine with fentanyl for spinal anesthesia.

Category

Treatment - Drugs

2**Description**

Intervention group: A group of addicts who will receive only intrathecal Marcaine for spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Gorgan's 5 Azar Educational and Medical center

Full name of responsible person

Dr. Mansour Deylami

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Gorgan Medical School, Shadravan Phalsaphy Higher Education Complex

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Professor Narges Begum Mirbehbahani

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Gorgan, 4 km, Sari, Golestan University of Medical Sciences, Gorgan, Iran. Deputy of Research and Technology of Gorgan, Gorgan, Gorgan

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gorgan 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**

Gorgan University of Medical Sciences

Full name of responsible person

Dr. Mansour Deylami

Position

Assistant professor of anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Position

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

2024

To whom data/document is available

Researcher working in academic institutions

Under which criteria data/document could be used

Without manipulation, mention the data reference

From where data/document is obtainable

Mansour.deylami@gmail.com, Gorgan University of
Medical Sciences

What processes are involved for a request to access data/document

Sending email, mention complete personal and job
details with documents

Comments