Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 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)

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+98 17 3115 3367

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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
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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
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Province
Golestan
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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
Street address
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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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