Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of morphine effect by intranasal and intravenous methods in orthopedic surgeries in the upper limb

Protocol summary

Study aim
Comparison of the effect of morphine by intranasal and intravenous methods in orthopedic surgeries in the upper limb in patients referred to 17 Shahrivar Amol Hospital in 1400

Design
Clinical trial with two intervention groups, one-way blind, randomized with permutation block randomization on 78 patients

Settings and conduct
The study site of the operating room of 17 Shahrivar Amol Hospital is on patients who are candidates for surgery on the upper limb, who will receive morphine for intravenous and intranasal methods to relieve pain. Blinding is done only by the analyzer.

Participants/Inclusion and exclusion criteria
Age 18- 65 years Upper limb fractures under general anesthesia Willingness to participate in the study Natural GCS Weight 60-100 kg Operating time up to 3 hours No underlying diseases No head injuries More than 12 breaths per minute Systolic blood pressure greater than 110 mm Hg SPO2 greater than 95% in room air

Intervention groups
In group A, people will receive 2 cc of intravenous morphine after surgery to relieve pain. In group B, people receive 2 cc of morphine intranasally using a dropper in each nostril 24 drops (48 drops in total).

Main outcome variables
Pain relief in the intranasal morphine group will be faster than intravenous and the side effects of the drug will be less.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210328050784N1**
Registration date: **2021-04-13, 1400/01/24**
Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**
Update count: **0**

Registration date
2021-04-13, 1400/01/24

Registrant information

Name
Nasrin Gaffari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3304 4000

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-21, 1400/02/01

Expected recruitment end date
2021-06-22, 1400/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of morphine effect by intranasal and intravenous methods in orthopedic surgeries in the upper limb

Public title
Comparative study of morphine effect by intranasal and intravenous methods in orthopedic surgeries

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate for orthopedic surgery for upper limb fractures under general anesthesia Agree to participate in the study Natural GCS (score 15) based on the Glasgow scale Weight between 60 to 100 kg Duration of operation up to 3 hours No underlying diseases including diabetes, liver and kidney disease, COPD and coagulation disorders Lack of sensitivity to drugs No addiction No head injuries during the accident More than 12 breaths per minute Systolic blood pressure greater than 110 mm Hg SPO2 More than 95% in room air
Exclusion criteria:
Dissatisfaction with continuing to participate in the project Prolongation of surgery time more than 3 hours
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple random sampling method will be used. Randomization block permutation was used to assign groups. Patients participating in the study will be divided into two groups of 39 using 4 blocks and letters A and B (for group equality). For block permutation randomization, the sealed envelope method with random sequence will be used. A sealed envelope containing the two letters A and B is inserted into the patient file, which is opened before the operation. People in group A will receive morphine intravenously and people in group B will receive intranasal morphine.
Blinding (investigator's opinion)
Single blinded
Blinding description
The blinding method will be one-way blind and only by the analyzer. Due to the knowledge of the facilitator and the researcher, as well as the patient about the method of using the drug, they will not be able to blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mazandaran University of Medical Sciences
Street address
Headquarters of Mazandaran University of Medical Sciences, The beginning of Valiasr Highway,Three ways Jouybar, Imam Square, Sari
City
Sari
Province
Mazandaran
Postal code
4815733971
Approval date
2021-01-27, 1399/11/08
Ethics committee reference number
IR.MAZUMS.REC.1399.911

Health conditions studied

1

Description of health condition studied
Orthopedic surgeries on the upper limbs
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative pain
Timepoint
10, 30, 60 minutes and 2 and 4 hours after drug administration
Method of measurement
VAS scale

2

Description
Nausea
Timepoint
10, 30, 60 minutes and 2 and 4 hours after drug administration
Method of measurement
VAS Nausea Scale

3

Description
Vomiting
Timepoint
10, 30, 60 minutes and 2 and 4 hours after drug administration
Method of measurement
Frequent vomiting: Less than once: Mild,Between 1-3 times: Medium,More than 3 times or howling: severe

4

Description
Itching
Timepoint
10, 30, 60 minutes and 2 and 4 hours after drug administration
Method of measurement
Asking: yes / no

5

Description
Vertigo
Timepoint
10, 30, 60 minutes and 2 and 4 hours after drug administration
Method of measurement
Asking: yes / no

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First: Use of 2 cc morphine by intravenous injection in recovery to relieve patient pain
Category
Treatment - Drugs

2

Description
Intervention group: Second: using 2 cc of morphine by intranasal method, which is poured into each nostril using 24 drops.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
17 Shahrivar Amol Hospital
Full name of responsible person
Nasrin Ghaffari vasati
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next to the Red Crescent, Red Crescent Street ,Amol,Mazandaran
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Sponsors / Funding sources

1

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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Nasrin Ghaffari vasati
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Surgical technology
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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It will not be published due to the dissatisfaction of the participants in publishing the information.
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The information and results obtained from the study will be published in the form of an article.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
If the data is not misused, they will be usable.
From where data/document is obtainable
Nasringhaffari.amo@gmail.com
What processes are involved for a request to access data/document
After the request, the results will be available to the applicant by email.
Comments