

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

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

Protocol summary

Registration timing: **prospective**

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

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

Update count: **0**

Registration date

2021-04-13, 1400/01/24

Design

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

Registrant information

Name

Nasrin Gaffari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3304 4000

Email address

nasringhaffari.amo@gmail.com

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.

Recruitment status

Recruitment complete

Funding source

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

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

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.

Scientific title

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210328050784N1**

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

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

Street address

next to the Red Crescent, Red Crescent Street ,Amol,Mazandaran

City

Amol

Province

Mazandaran

Postal code

۴۲۲۴۰۰۱۰۱۱

Phone

+98 11 4422 4001

Email

tajnoor2010@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Headquarters of Mazandaran University of Medical Sciences, The beginning of Valiasr Highway, Three ways Jouybar, Imam Square, Sari

City

Amol

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3304 4000

Email

publicrel@mazums.ac.ir

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

Street address

17 Shahrivar Amol Hospital, Mazandaran

City

Amol

Province
Mazandaran
Postal code
9691738135
Phone
+98 11 4422 4002
Email
nasringhaffari.amo@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Hooshang Akbari
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Bouali Hospital, Sari, Mazandaran
City
Sari
Province
Mazandaran
Postal code
96917383135
Phone
+98 11 3334 4507
Email
Hooshangakbari48@yahoo.com

Person responsible for updating data

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
Street address

end of the sea 1/22, Adl building, second floor, unit 4,
Amol, Mazandaran

City
Amol
Province
Mazandaran
Postal code
9691738135
Phone
+98 11 4308 6154
Email
nasringhaffari.amo@gmail.com

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