# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

04 Jul 2026

## Comparative study Intraoperative methadone and morphin for postoperative pain after rhinoseptoplasty

## Protocol summary

**Study aim**
Determining and comparing the effect of methadone and morphine on pain after rhinoseptoplasty surgery

**Design**
In the main and studied group, the desired dose of the drug is 0.15 mg per body weight (ideal weight). Methadone is administered slowly intravenously half an hour after the start of surgery. In the study group, the desired dose of the drug was 0.15 mg per body weight (ideal weight). Morphine is administered slowly intravenously half an hour after surgery.

**Settings and conduct**
This study is conducted in a double-blind manner, that is, patients, doctors, caregivers, and statistical analysts will not know about the allocation of groups to reduce bias. . During the operation, hemodynamic variables were recorded and recorded with the results. We compare the results of the control group. In case and control groups, follow-up, study and recording of variables identified at the end of surgery and patient extubation and recovery and 1 and 6 hours after surgery by the researcher include: variables such as nausea and vomiting and bleeding, the amount of analgesic and sedative use, headache and severity Postoperative pain (according to the VAS table) and using the pain observation scale, the frequency of headache, postoperative nausea and vomiting and the amount of analgesia used 6 hours after surgery will be evaluated and then compared.

**Participants/Inclusion and exclusion criteria**
Candidate patients for rhinoplasty surgery ECG normal and (no long QT)

**Intervention groups**
In the main and studied group, the desired dose of the drug is 0.15 mg per body weight (ideal weight). Methadone is administered slowly intravenously half an hour after the start of surgery.

**Main outcome variables**
Intensity of pain/ Hemodynamics

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220517054884N1**
Registration date: **2023-08-13, 1402/05/22**
Registration timing: **retrospective**

Last update: **2023-08-13, 1402/05/22**
Update count: **0**

**Registration date**
2023-08-13, 1402/05/22

**Registrant information**

**Name**
Vahid Damanpak

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-06-10, 1401/03/20

**Expected recruitment end date**
2023-03-23, 1402/01/03

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Comparative study Intraoperative methadone and morphin for postoperative pain after rhinoseptoplasty

**Public title**
Comparison of the effect of methadone and morphine on pain
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Candidate patients for rhinoseptoplasty surgery Normal EKG and (no long QT)
**Exclusion criteria:**
Drug addiction History and psychological illness Patient dissatisfaction History of drug allergy to previous surgeries
**Age**
No age limit
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **182**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization is performed using random block allocation with 4 blocks, which have all four modes A, A, B, B, AA B, B B A A and B A A B A, A B B A, B A A A B, written in 6 cards and The first four patients are randomly grouped. The ward manager takes the patient card out of the bag and the patients are divided into groups by lot. For example, if lottery a A b b The first and second patients are in the first group and the third and fourth patients are in the second group and also for the next four patients, a card is issued again. The anesthesia and injection stage will be performed by an anesthesiologist and The questionnaire is reviewed and completed by an anesthesiologist in the operating room and recovery. Describe how to blind
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
This study is conducted in a double-blind manner, that is, patients, doctors, caregivers, and statistical analysts will not know about the allocation of groups to reduce bias. In these studies, random assignment is used to allocate patients into two groups: the experimental group and the control group. Researchers and participants are made aware of who is in which group. The study will be conducted in a way that the surgeon, nurses, patients, and the data analyst will not know the type of painkillers injected into the control and intervention groups. Statistical analyst will be selected from outside the treatment team to ensure double-blindness of the study to a large extent. When the patient is not aware of the type of medicine received, the effect of the patient's personal characteristics and psychological aspect on the research results is reduced. Researchers are unaware of which type of painkillers the participant receives. Therefore, the impact of the doctor's judgments in evaluating the clinical symptoms and the patient's pain after surgery is minimized. By using this method, we try to reduce the effect of possible biases in the results (the effect of methadone and morphine in reducing pain).
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Qom University of Medical Sciences
**Street address**
Alley 1, Safashahr St.
**City**
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**Province**
Ghoum
**Postal code**
3714816335
**Approval date**
2022-05-12, 1401/02/22
**Ethics committee reference number**
IR.MUQ.REC.1401.012

## Health conditions studied

### 1

**Description of health condition studied**
Comparison of the effect of methadone and morphine on pain after rhinoseptoplasty surgery
**ICD-10 code**
R52
**ICD-10 code description**
Acute Pain

## Primary outcomes

### 1

**Description**
Pain after surgery
**Timepoint**
The study compares the effect of methadone and morphine on pain after rhinoseptoplasty surgery to

measure pain half an hour after surgery and at the end of surgery , patient extubation and recovery 1 and 6 hours after surgery.

**Method of measurement**

In the study "Comparative study of the effect of methadone and morphine on pain after rhinoseptoplasty surgery" is the method of measuring the outcome variable using a clinical information checklist and the second part is the use of a standard pain intensity questionnaire (Visual Analogue Scale) to determine pain intensity in patients. The Visual Analogue Scale (VAS) is a subjective measure of pain. It consists of a 10cm line with two endpoints representing ‘no pain’ and ‘worst pain imaginable’. Patients are asked to rate their pain by placing a mark on the line corresponding to their current level of pain. The distance along the line from the ‘no pain’ marker is then measured with a ruler giving a pain score out of 10.

### 2

**Description**

Hemodynamic variables. (blood pressure, Saturation of Peripheral Oxygen)

**Timepoint**

The study compares the effect of methadone and morphine on pain after rhinoseptoplasty surgery to measure Hemodynamic variables half an hour after surgery and at the end of surgery , patient extubation and recovery 1 and 6 hours after surgery.

**Method of measurement**

Mercury sphygmomanometer.( for the measurement of blood pressure ).Pulse Oximeter (for the measurement of Saturation of Peripheral Oxygen)

### 3

**Description**

Saturation of Peripheral Oxygen

**Timepoint**

The study compares the effect of methadone and morphine on pain after rhinoseptoplasty surgery to measure (Saturation of Peripheral Oxygen )half an hour after surgery and at the end of surgery , patient extubation and recovery 1 and 6 hours after surgery.

**Method of measurement**

Pulse Oximeter

### 4

**Description**

blood pressure

**Timepoint**

The study compares the effect of methadone and morphine on pain after rhinoseptoplasty surgery to measure (blood pressure ) half an hour after surgery and at the end of surgery , patient extubation and recovery 1 and 6 hours after surgery.

**Method of measurement**

Mercury sphygmomanometer

## Secondary outcomes

### 1

**Description**

In the study "Comparative study of the effect of methadone and morphine on pain after rhinoseptoplasty" the secondary outcome could be "hemodynamic changes".

**Timepoint**

The patient hemodynamics are recorded at the end of the operation, patient extubation and recovery and 1 and 6 hours after surgery.

**Method of measurement**

In this study, using the patient's personal and clinical information checklist, including blood pressure and heart rate and blood oxygen saturation.

## Intervention groups

### 1

**Description**

Intervention group: n the main and studied group, the desired dose of the drug is 0.15 mg per body weight (ideal weight). Methadone is administered slowly intravenously half an hour after the start of surgery.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In this group, the desired dose of the drug is 0.15 mg per body weight (ideal weight). Morphine is administered slowly intravenously half an hour after the start of surgery.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Forghani Hospital

**Full name of responsible person**

Dr. Vahid Daman Pak Moghadam

**Street address**

Azar St., next to the gas station, Forghani Hospital

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## Sponsors / Funding sources

**1**

**Sponsor**
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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**
The University of Qom
**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

**2**

**Sponsor**
**Name of organization / entity**
Qom Medical Sciences Research Deputy
**Full name of responsible person**
Dr. Alireza Kuhpaei
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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**
Qom Medical Sciences Research Deputy
**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**
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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**
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**
It can be published as much as possible
**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**
Researchers working in academic and scientific institutions
**Under which criteria data/document could be used**
Results only
**From where data/document is obtainable**
Dr. Daman Pak Forqani Hospital
**What processes are involved for a request to access data/document**
Using the email educationmo110@gmail.com
**Comments**