

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of analgesic and hemodynamic effects of morphine sulphate alone and morphine sulphate plus nitroglycerine in candidates for simple abdominal surgeries using intravenous patient-controlled analgesia

Protocol summary

Study aim

To examine the effect of adding nitroglycerin to morphine in patient-controlled analgesia pumps on the pain following simple abdominal surgeries

Design

A total of 60 candidates for simple abdominal surgeries will be assigned into case and control groups using the table of random numbers (30 patients per group).

Settings and conduct

The study is one-centered, single-blinded (on the part of participants), and in the second phase of clinical trials.

Participants/Inclusion and exclusion criteria

The major inclusion criteria are: patients with anesthesia classes 1 and 2; age from 18 to 50 years; and being candidate for simple elective abdominal surgery. The major exclusion criteria include addiction, history of using any kinds of sedatives or anti-nausea/vomiting drugs; and contraindication and sensitiveness to nitroglycerin drugs and morphine.

Intervention groups

Without receiving any pre-anesthetics, both groups undergo the required monitoring and examinations in the operating room, including the measurement of systolic and diastolic blood pressure in a non-invasive manner; the measurement of arterial oxygen; pulse oximetry; and electrocardiogram recording. Patients in the two groups undergo general anesthesia in a similar manner using 2 milligram/kilogram propofol and 3 microgram/kilogram fentanyl, as well as 0.5 milligram/kilogram muscle relaxant with a tracheal tube of appropriate size. After the surgery is completed and the patient is transferred to the recovery unit, the intravenous pain pump in the control group will be filled with morphine 0.75 milligram/kilogram, and it will be filled in the case group with morphine 0.5 milligram/kilogram plus 3 microgram/minute nitroglycerin; normal saline will be used in order to fill up the remaining volume of the pump

up to 100 cc, and then it will be attached to the patient by inserting a separate vein with angiocatheter No. 20.

Main outcome variables

Hemodynamic parameters, nausea, vomiting and pain will be measured using the visual analogue scale, and sedation will be measured based on Ramsay scale immediately, 2, 6, 12 and 24 hours after operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140519017756N33**

Registration date: **2018-01-27, 1396/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-27, 1396/11/07**

Update count: **0**

Registration date

2018-01-27, 1396/11/07

Registrant information

Name

Mohammad Bagher Roozgar

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-21, 1395/10/01
Expected recruitment end date
 2018-05-21, 1397/02/31
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Comparison of analgesic and hemodynamic effects of morphine sulphate alone and morphine sulphate plus nitroglycerine in candidates for simple abdominal surgeries using intravenous patient-controlled analgesia

Public title
 The effect of adding nitroglycerin to morphine in intravenous pain control pumps

Purpose
 Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with anesthesia classes 1 and 2 age from 18 to 50 years candidate for simple elective abdominal surgery (herniorrhaphy, cholecystectomy, jejunioileostomy) with surgery duration below two hours bleeding volume less than 200 cc length of incision below 10 centimeters
Exclusion criteria:
 Addiction history of using any kinds of sedatives or anti-nausea/vomiting drugs contraindication and sensitiveness to nitroglycerin drugs and morphine incidence of side-effects such as hypotension, headaches, nausea/vomiting, or arrhythmia requiring treatment during the use of pumps cases of turning surgeries into complex ones

Age
 From **18 years** old to **50 years** old

Gender
 Both

Phase
 2

Groups that have been masked

- Participant

Sample size
 Target sample size: **60**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Table of random numbers

Blinding (investigator's opinion)
 Single blinded

Blinding description
 Patients are not aware of which study group they are allocated into.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Ghaffari St.,

City

Birand

Province

South Khorasan

Postal code

9717853577

Approval date

2016-12-03, 1395/09/13

Ethics committee reference number

IR.bums.REC.1395.194

Health conditions studied

1

Description of health condition studied

Post-operative pain

ICD-10 code

G89.28

ICD-10 code description

Other chronic postprocedural pain

Primary outcomes

1

Description

Pain

Timepoint

Immediately, 2, 6, 12 and 24 hours after operation

Method of measurement

Visual Analogue Scale

2

Description

Systolic and diastolic blood pressure

Timepoint

Immediately, 2, 6, 12 and 24 hours after operation

Method of measurement

Saadat Company Monitoring Device

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

Immediately, 2, 6, 12 and 24 hours after operation

Method of measurement

Examination

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

Intervention group: (Morphine + Nitroglycerin): Intravenous pain pump of the case group will be filled with 0.5 milligram/kilogram morphine + 3 microgram/minute nitroglycerin.

Category

Prevention

2**Description**

Control group: (morphine): Intravenous pain pump in the control group will be filled with 0.75 milligram/kilogram morphine .

Category

Prevention

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

Operating Room of Imam Reza Hospital

Full name of responsible person

Dr Seyed Hasan Karbasy

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Taleghani St.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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

Birjand University of Medical Sciences

Proportion provided by this source

50

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**

Birjand University of Medical Sciences

Full name of responsible person

Dr Azadeh Sekhavati

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

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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

The majority of participants agreed to participate if the confidentiality of data would be guaranteed.

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

Yes - There is a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Informed Consent for Participation

When the data will become available and for how long

Unlimited

To whom data/document is available

Any researcher

Under which criteria data/document could be used

To complete and to express viewpoints

From where data/document is obtainable

The official website of Vice-chancellery for Research of Birjand University of Medical Sciences

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

Direct access to the website

Comments