

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of adding trinitroglycerin (TNG) to the patient controlled intravenous analgesia pump in patients with lower limb orthopedic surgery

Protocol summary

Study aim

The aim of current study is to survey effects of adding trinitroglycerin (TNG) to the patient controlled intravenous analgesia pump in patients with lower limb orthopedic surgery

Design

Clinical trial study, with parallel groups, double blinded, randomized

Settings and conduct

75 patients who undergo surgery due to fracture of the lower limbs in Rasul Akram hospital were selected and were randomly per muted blocks and based on online randomization software, divided into three equal groups and received one of following analgesia methods via intravenous pain pump after the end of surgery in recovery: Control group: Without using Trinitriglycerin (TNG). First intervention group: Using 500 microgram (mcg) Trinitriglycerin (TNG) in the pain pump. Second intervention group: Using 1000 mcg, TNG in the pain pump. Pain in patients is measured 4, 8, 12 and 24 hours after surgery by Visual analogue scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Lower extremities orthopedic patients, Spinal anesthesia with 15 milligram (mg) bupivacain 0.5%, Patients with American Society of Anesthesiologists (ASA) I,II. Exclusion criteria: Addiction to alcohol, benzodiazepines and opium, Heart failure, Patients dissatisfaction, Allergies to any of used drugs, Seizure, Valvular heart disease, Arrhythmia.

Intervention groups

First intervention group: Using 500 microgram (mcg) Trinitriglycerin (TNG) in the pain pump. (Nitral, Caspian Tamin Pharmaceutical Co.) Second intervention group: Using 1000 mcg, TNG in the pain pump. Control group: Pain pump without using TNG in the pain pump

Main outcome variables

Patient's pain 4, 8, 12 and 24 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180922041088N1**

Registration date: **2018-12-28, 1397/10/07**

Registration timing: **retrospective**

Last update: **2018-12-28, 1397/10/07**

Update count: **0**

Registration date

2018-12-28, 1397/10/07

Registrant information

Name

Atossa Soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

atossa61@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-01, 1396/06/10

Expected recruitment end date

2018-08-01, 1397/05/10

Actual recruitment start date

2017-10-07, 1396/07/15

Actual recruitment end date

2018-09-11, 1397/06/20

Trial completion date

2018-10-17, 1397/07/25

Scientific title

Effects of adding trinitroglycerin (TNG) to the patient controlled intravenous analgesia pump in patients with lower limb orthopedic surgery

Public title

Effects of nitroglycerine (TNG) in intravenous pain control pump

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Lower extremities orthopedic patients Spinal anesthesia with 15 milligram (mg) bupivacain 0.5% Patients with American Society of Anesthesiologists (ASA) I,II

Exclusion criteria:

Addiction to alcohol, benzodiazepines and opium. Heart failure Patients dissatisfaction Allergies to any of used drugs Seizure Valvular heart disease Arrhythmia

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

First, individuals who have the characteristics necessary to enter the study are usually taken from a non-random sample using a simple sampling method. Then, randomization is done between study groups. In this study, a block randomization method (including 4 blocks) is used. One of the study partners who has not been blindfolded, named pain pump with and without TNG with the letters A and B. Then, the researcher will distribute A and B packages among patients in a randomized block method (ABAB, BABA, AAB, BBAA, ABBA, BAAB; A, first person; B, Second person; A, third person; B, fourth person B etc.). Then, selecting the blocks are continued until reaching the sample size. Random sequence generation was done using simple randomization. To construct a random sequence to the possible blocks (6 blocks), we give numbers to them from one to six numbers. According to the sample size, each number of 4 blocks required will be used. the number of blocks was chosen from the random numbers table and based on these numbers we identified the sequence of blocks in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study blinding will be as follows: Researcher and data collector are the same and are blinded and unaware of the contents of the pain pumps. Patients: Are blinded

because they are unaware of the contents of the pain pump. Blinding: Based on the sequence of random numbers, group A or B will be placed inside sealed envelopes. A researcher who does not know the contents and sequence of envelopes will open the envelopes accordingly, and based on the fact that A or B has arrived, they will use a pre-filled pump A or B, respectively. One of the members of the research team has put the A label or label B on the pumps (only the same person is aware of the contents inside the pump)

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences., next to Milad Tower., Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2017-11-01, 1396/08/10

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9411174009

Health conditions studied**1****Description of health condition studied**

pain control after surgery

ICD-10 code

M79.6

ICD-10 code description

Pain in limb, hand, foot, fingers and toes

Primary outcomes**1****Description**

Pain after lower limb orthopedic surgery

Timepoint

4, 8, 12 and 24 hours after surgery

Method of measurement

Using Visual Analogue Scale

Secondary outcomes

1

Description

Complications

Timepoint

During 24 hours after surgery

Method of measurement

With physical examination

2

Description

Need for adjuvant analgesic

Timepoint

During 24 hours using pain pump

Method of measurement

Using questionnaire information

Intervention groups

1

Description

First intervention group: Patients will use 500 microgram (mcg) Trinitroglycerin (TNG)-containing pain pump to reduce pain after lower limb orthopedic surgery. (Nitral, Caspian Tamin Pharmaceutical Co.)

Category

Treatment - Drugs

2

Description

Control group: Patients will use without Trinitroglycerin (TNG)-containing pain pump to reduce pain after lower limb orthopedic surgery

Category

Treatment - Drugs

3

Description

Second intervention group: Patients will use 1000 microgram (mcg) Trinitroglycerin (TNG)-containing pain pump to reduce pain after lower limb orthopedic surgery. (Nitral, Caspian Tamin Pharmaceutical Co.)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Poupak Rahim Zadeh

Street address

Department of pain, 4th Floor, Hazrat-E-Rasool Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

We have not yet set a conclusion

When the data will become available and for how long

We have not yet set a conclusion

To whom data/document is available

We have not yet set a conclusion

Under which criteria data/document could be used

We have not yet set a conclusion

From where data/document is obtainable

We have not yet set a conclusion

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

We have not yet set a conclusion

Comments