

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the Effect of Transdermal Nitroglycerine on Postoperative Analgesia Following Orthopedic Surgery under Spinal Anesthesia with Sufentanil and Lidocaine

Protocol summary

Summary

Background & Objective: Administration of intrathecal opioid is one of the postoperative analgesia management methods. Experimental data suggests transdermal nitroglycerine (a nitric oxide generator) can enhance analgesic effect of opioids. This study was done to assess the effect of transdermal nitroglycerine on the patients undergoing orthopedic surgery. Material and Methods: In this prospective, double blinded, clinical trial, 24 patients scheduled for plating of tibia or fibula were randomized to one of two groups. In all of the patients, spinal anesthesia was done with lidocaine 5% (100 mg) and sufentanil (5 µg). After 25 minutes, in 12 patients (nitroglycerine group) transdermal nitroglycerine patch and in the other 12 patients (placebo group) placebo patch was applied at the thorax. Duration of analgesia, pain occurrence, analgesic consumption and visual analogue scale (VAS) in 24 hours after operation were assessed. Data were analyzed by SPSS 11th version, with t-test and Fisher exact test. $P < 0.05$ was considered significant.

General information

Acronym

NTG

IRCT registration information

IRCT registration number: **IRCT138905124498N1**

Registration date: **2004-09-22, 1383/07/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2004-09-22, 1383/07/01

Registrant information

Name

Maryam Davoudi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1264 0030

Email address

davoudi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan university of medical sciences

Expected recruitment start date

2004-09-22, 1383/07/01

Expected recruitment end date

2005-03-19, 1383/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Transdermal Nitroglycerine on Postoperative Analgesia Following Orthopedic Surgery under Spinal Anesthesia with Sufentanil and Lidocaine

Public title

Effect of Transdermal Nitroglycerine on Postoperative Analgesia

Purpose

Prevention

Inclusion/Exclusion criteria

24 patients scheduled for tibia or fibula plating with ASA class I or II, 18 to 40 years included in study. Exclusion

criteria were: history of NTG or lidocaine allergy, history of opium addiction, chronic use of analgesics, circulatory failure, cardiogenic shock and severe hypotension.

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamadan university of medical sciences

Street address

Shahid Fahmideh blvd

City

Hamadan

Postal code

Approval date

2004-07-12, 1383/04/22

Ethics committee reference number

897/51/16/پ

Health conditions studied

1

Description of health condition studied

Lower leg fracture

ICD-10 code

S82

ICD-10 code description

Fracture of lower leg, including ankle

Primary outcomes

1

Description

Postoperative analgesia duration

Timepoint

24 hours after operation

Method of measurement

First rescue analgesic request(hours)

Secondary outcomes

1

Description

Postoperative analgesic consumption

Timepoint

24 hours after operation

Method of measurement

Data were recorded in the relevant forms

2

Description

Pain score

Timepoint

24 hours after operation

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

In the placebo group placebo patch was applied in chest area outside the blocked area and left there for 24 hours. Both groups received intravenous infusion at 10 ml/kg

Category

Placebo

2

Description

In the intervention group transdermal nitroglycerine patch was applied in chest area outside the blocked area and left there for 24 hours. Both groups received intravenous infusion at 10 ml/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mobasher Kashani hospital

Full name of responsible person

Maryam Davoudi

Street address

Besat hospital

City

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan university of medical sciences

Full name of responsible person

Hosein Emad Momtaz

Street address

Shahid Fahmideh blvd

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamadan university of medical sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan university of medical sciences

Full name of responsible person

Maryam Davoudi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Besat hospital

City

Hamadan

Postal code

Phone

+98 81 1264 0030

Fax

+98 81 1265 1515

Email

davoudi@umsha.ac.ir; mdavoudi10@yahoo.com

Web page address

umsha.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Hamadan university of medical sciences

Full name of responsible person

Maryam Davoudi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Besat hospital

City

Hamadan

Postal code

Phone

+98 81 1264 0030

Fax

+98 81 1265 1515

Email

davoudi@umsha.ac.ir; mdavoudi10@yahoo.com

Web page address

umsha.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Hamadan university of medical sciences

Full name of responsible person

Maryam Davoudi

Position

Anesthesiologist

Other areas of specialty/work

Street address

Besat hospital

City

Hamadan

Postal code

Phone

+98 81 1246 0030

Fax

+98 81 1265 1515

Email

davoudi@umsha.ac.ir; mdavoudi10@yahoo.com

Web page address

umsha.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

