

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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*

