Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 g). 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

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Maryam Davoudi
Name of organization / entity
Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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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 severte 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

Hamadan

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

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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

Data Dictionary	*empty*