

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the pain control effects of Nitroglycerine versus placebo during the Propofol injection

Protocol summary

Summary

This study was performed to evaluate the effects of Nitroglycerine on pain severity in patients undergoing Propofol injection. 100 American society of anesthesiologist class I and II patients, candidate for open leg wound surgeries were selected. Moreover, none of the participants had thin dorsal veins and any history of receiving analgesia or sedation within last 24 hours. Patients were randomly assigned to case and control groups (n=50 for each). patients in the case group were given 200 microgram nitroglycerine ,diluted in 5 milliliter of saline intra venous from left arm. Patients in the control group received 5 milliliter of saline intra venousfrom left arm.Twenty seconds later, 100 mg of propofol were kept at room temperature was injected. propofol was administered for a period of 5 seconds. Any behavioral signs such as facial grimacing, arm withdrawal or tears and Visual analogue scale were noted by the anesthesiologist. also mean arterial blood pressure, diastolic and systolic blood pressure with a sphygmomanometer are noted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112720112N1**

Registration date: **2014-12-15, 1393/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-15, 1393/09/24

Registrant information

Name

Pooya Derakhshan

Name of organization / entity

Birjand Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2012-02-01, 1390/11/12

Expected recruitment end date

2013-02-01, 1391/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the pain control effects of Nitroglycerine versus placebo during the Propofol injection

Public title

Effects of Nitroglycerine on pain during Propofol injection

Purpose

Treatment

Inclusion/Exclusion criteria

Participant inclusion criteria: American society of anesthesiologists class I and II patients; age between 18-70 years. exclusion criteria: thin dorsal hand veins; history of receiving analgesia or sedation within last 24 hours.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Birjand University of Medical Sciences

Street address
N:56, Ghafari Ave.

City
Birjand

Postal code
1973456783421589

Approval date
2011-07-22, 1390/04/31

Ethics committee reference number
735

Health conditions studied

1

Description of health condition studied
Open wound of leg

ICD-10 code
S81.9

ICD-10 code description
Open wound of lower leg, part unspecified

Primary outcomes

1

Description
pain

Timepoint
every 30 Secondes

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description
Blood pressure

Timepoint
every 3 minutes

Method of measurement
sphygmomanometer

Intervention groups

1

Description
200 microgram nitroglycerine diluted in 5 milliliter of saline.

Category
Treatment - Drugs

2

Description
5 milliliter of saline.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Pooya Derakhshan

Street address
Imam Reza Hostipal, Taleghani St.

City
Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Hasan Karbasi

Street address
Ghafari Ave.

City
Birjand

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
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

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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