

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the analgesic effect of Nitroglycerin added to lidocaine in intravenous regional anesthesia in hand Surgery.

Protocol summary

Summary

In this double-blind randomized clinical trial, 60 ASA I and II patients, candidate for hand and Forearm surgeries (tendon injuries) aging from 18 to 50 years. The exclusion criteria were sickle cell anemia, hypersensitivity, G6PD, Raynaud's disease, drug abuse history and addiction, and open fracture. The selected patients were randomly assigned (with a simple random manner) to receive either 200 microgram Nitroglycerin plus 3mg/kg lidocaine 2% diluted with saline to a total dose of 40 mL or only lidocaine 2% diluted with saline to a total dose of 40 mL (each group 30 subjects). Sensory and motor block onset time, recovery time, need to fentanyl, Quality of Anesthesia Assessed by Patients and Surgeon, tourniquet time and vas were understudy variables. Data from 60 patients were analyzed using SPSS (version 18.0) software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105136465N1**
Registration date: **2011-06-11, 1390/03/21**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-11, 1390/03/21

Registrant information

Name

Seyed Alireza Seyed Siamdoust

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the analgesic effect of Nitroglycerin added to lidocaine in intravenous regional anesthesia in hand Surgery.

Public title

Effect of Nitroglycerin added to lidocaine in bier block

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: 60 ASA I and II patients; candidate for hand and forearm surgeries (tendon injuries); under 90 min; aging from 18 to 50 years. exclusion criteria: sickle cell anemia; hypersensitivity; G6PD; Raynaud's disease; drug abuse history and addiction; and open fracture.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

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

Tehran University of Medical Sciences Ethics Committee

Street address

Shahid Hemmat Highway , Pardis Hemmat , Vice chancellor for research, Tehran University of Medical Sciences

City

Tehran

Postal code

1969714713

Approval date

2011-03-07, 1389/12/16

Ethics committee reference number

43107

Health conditions studied

1

Description of health condition studied

Injury of muscle and tendon at wrist and hand level

ICD-10 code

S66

ICD-10 code description

Injury of muscle and tendon at wrist and hand level

Primary outcomes

1

Description

Sensory block onset time

Timepoint

Every thirty seconds to completion of sensory block.

Method of measurement

Shortbeveled needle.

2

Description

Motor block onset time

Timepoint

Every thirty seconds to completion of motor block.

Method of measurement

Asking the subject to flex and extend his wrist and fingers.

3

Description

Sensory recovery time

Timepoint

Every thirty seconds to return of sense in hand.

Method of measurement

Shortbeveled needle

4

Description

Motor block recovery time

Timepoint

Every thirty seconds to complete movement of wrist.

Method of measurement

Movement of wrist

Secondary outcomes

1

Description

Tourniquet time

Timepoint

Every 20 minutes to start of pain.

Method of measurement

Visual analog scale (VAS) (0 cm _ "no pain" and 10 cm _ "worst pain imaginable.

2

Description

Need to fentanyl

Timepoint

At the end of the surgery.

Method of measurement

Microgram

Intervention groups

1

Description

Adding 200 microgram TNG plus 3 mg/kg lidocaine 2% dilute in 40 ml saline in nitroglycerine group.

Category

Treatment - Drugs

2

Description

Adding salin 40 ml as Placebo to 3 mg/kg lidocaine 2% in control group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Fatemeh Hospital

Full name of responsible person

Seyed Ali Reza Seyed Siamdoust

Street address

19 Ave . Seyed Jamal Aldine Asadabadi St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotohi

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Shahid Hemmat Highway , Tehran University of Medical Sciences

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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

Vice chancellor for research, Tehran 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

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Full name of responsible person

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Position

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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