Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Phase 2 Study of Assessing the Effect of Ultra-Low-Dose Naloxone on Accentuating the Effect of Fentanyl on Enhancing the Local Anesthetic Characteristic of Lidocaine

Protocol summary

Summary

The study will evaluate the effectiveness of an ultra-low dose of naloxone added to lidocaine-fentanyl solution in enhancing the block quality & duration of action of the anesthetic solution in axillary plexus block. We will study Distal Radius Fractures in 4 groups. In the first group, lidocaine alone will be used for the block. In the second group, lidocaine solution containing naloxone, without fentanyl, in the 3rd group, lidocaine solution containing fentanyl without naloxone & in the 4th group, lidocaine solution containing fentanyl & naloxone will be used for the block. Onset time, duration of action & post-op. pain will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138711211666N1**
Registration date: **2009-02-12, 1387/11/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2009-02-12, 1387/11/24

Registrant information

Name

Behrang Nooralishahi

Name of organization / entity

TehranUMS

Country

Iran (Islamic Republic of)

Phone

+98 849023723

Email address

nooralishahi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-02-19, 1387/12/01

Expected recruitment end date

2009-06-18, 1388/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Phase 2 Study of Assessing the Effect of Ultra-Low-Dose Naloxone on Accentuating the Effect of Fentanyl on Enhancing the Local Anesthetic Characteristic of Lidocaine

Public title

The Effect of Ultra-Low Dose of Naloxone Added to Lidocaine-Fentanyl Mixture on Axillary Brachial Plexus Blockade

Purpose

Other

Inclusion/Exclusion criteria

Inclusion Criteria: Distal Radius Fracture; Exclusion Criteria: Diabetes mellitus, Addiction, Recent analgesic or narcotic medication.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2
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
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic comittee, faculty of medicine
Street address
Faculty of medicine, Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
empty
Ethics committee reference number
322/6311

Health conditions studied

1

Description of health condition studied
Fracture of distal of radius
ICD-10 code
S52.5
ICD-10 code description
Fracture of lower end of radius

2

Description of health condition studied
Local Anesthesia
ICD-10 code
Y48.3
ICD-10 code description
Local anaesthetics

Primary outcomes

1

Description
Block Time
Timepoint
every 15 minutes
Method of measurement
Pinprick test

Secondary outcomes

1

Description
post operative pain
Timepoint
every 4 hrs
Method of measurement
VAS (visual analog scale)

Intervention groups

1

Description
34ml 1.5% lidocaine solution containing 100 ng naloxone
Category
Other

2

Description
34ml 1.5% lidocaine alone
Category
Other

3

Description
34ml 1.5%lidocaine solution containing 100 microgram fentanyl
Category
empty

4

Description
34ml 1.5% lidocaine solution containing 100 microgram fentanyl & 100 ng naloxone
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati General Hospital
Full name of responsible person
Ali Movafegh
Street address

Shariati Hosp, North Karegar Ave, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhoondzadeh

Street address

Tehran University of Medical Sciences, Vice Chancellor for research

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

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

Anesthesiology Dep, Tehran University of Medical Sciences

Full name of responsible person

Ali Movafegh

Position

Assoc. Prof.

Other areas of specialty/work

Street address

Anesthesiology Dep, Shariati Hosp.

City

Tehran

Postal code

Phone

+98 21 8490 2372

Fax

Email

movafegh@sina.tums.ac.ir, ali@movafegh.com

Web page address

www.movafegh.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Anesthesiology Dep, Tehran University of Medical Sciences

Full name of responsible person

Ali Movafegh

Position

Assoc. Prof.

Other areas of specialty/work

Street address

Shariati Hosp, North Karegar Ave, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 8490 2372

Fax

Email

movafegh@sina.tums.ac.ir, ali@movafegh.com

Web page address

www.movafegh.com

Person responsible for updating data

Contact

Name of organization / entity

Anesthesiology Dep, TehranUMS

Full name of responsible person

Behrang Nooralishahi

Position

Resident

Other areas of specialty/work

Street address

Shariati Hosp, North Karegar Ave, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 8490 2373

Fax

Email

nooralishahi@razi.tums.ac.ir, bnooralishahi@hotmail.com

Web page address

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*