Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of adding sufentanil to marcaine solution 0.5% on the onset and duration of supraclavicular nerve block in addict and non addict patients

Protocol summary

Summary

Objectives:Understanding the effect of opium addiction on the clinical practice is becoming a necessity due to the high prevalence. Design:Double Blinded Clinical Trial Setting and Conduct: Dr. Shariati Hospital Operating Room Participants:120 patients,aged 18-60 years old who are candidate for upperlimb surgery under supraclavicular block, are selected and are randomized into 4 groups. Patients with a history of chronic pain or allergies to study drug protocol,and renal or liver disease are excluded from the study. Intervention: Group 1, no history of opium addiction,receive 30 milliliters of bupivacaine 0.5%along with 2 milliliters saline as placebo; Group 2, No history of opium addiction, receive 30 milliliters bupivacaine 0.5% along with 2 milliliters sufentanil (10 micrograms); Group 3, Positive history of opium addiction, receive 30 milliliters bupivacaine 0.5% along with 2 milliliters saline as placebo; Group 4, positive history of opium addictions , receive 30 milliliters of bupivacaine along with 2 milliliters sufentanil (10 micrograms). Main outcome measures:Onset time and length of sensory and motor blocks are recorded in the 4 groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201209165140N5**
Registration date: **2014-03-11, 1392/12/20**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Omid Azimaraghi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2206 6194

Email address

cazimaraghi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research-Tehran University of Medical Sciences-

Expected recruitment start date

2014-04-01, 1393/01/12

Expected recruitment end date

2014-05-01, 1393/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding sufentanil to marcaine solution 0.5% on the onset and duration of supraclavicular nerve block in addict and non addict patients

Public title

Supraclavicular nerve block in addicts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: A body mass index (BMI) less than 30 kilograms per cubic meter;American Society of anesthesiologists physical status class I and II;Elective forearm and arm surgery less than 180 minutes

Exclusion criteria: Study protocol drug allergy ;Hepatic or renal disease ;An addiction to benzodiazepines or other non opioid substances;Pregnant women ;History of chronic pain

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee, Faculty of medicine of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Faculty of Medicine,Poorsina street ,Keshavarz avenue,

City

Tehran

Postal code

Approval date

2013-03-20, 1391/12/30

Ethics committee reference number

846/13684

Health conditions studied

1

Description of health condition studied

Regional anesthesia

ICD-10 code

R29.8

ICD-10 code description

نشانه ها و علایم نامشخص شامل سیستم عصبی و سیستم عضلانی و استخوانی

Primary outcomes

1

Description

Nerve block Duration

Timepoint

every 15 minutes

Method of measurement

pinprick test

Secondary outcomes

1

Description

Onset of nerve block

Timepoint

every 5 minutes

Method of measurement

pinprick test

Intervention groups

1

Description

Patients in group 1 are administered the mentioned solution below in a single shot in the supraclavicular nerve block for upper limb regional anesthesia. Group 1, no history of opium addiction,receive 30mL of bupivacaine 0.5%along with 2 mL saline as placebo(control group)

Category

Treatment - Drugs

2

Description

Patients in group 2 are administered the mentioned solution below in a single shot in the supraclavicular nerve block for upper limb regional anesthesia. Group 2, No history of opium addiction who receive 30mL bupivacaine 0.5% along with 2mL sufentanil (10µg); (intervention)

Category

Treatment - Drugs

3

Description

Patients in group 3 are administered the mentioned solution below in a single shot in the supraclavicular nerve block for upper limb regional anesthesia. Group 3, Positive history of opium addiction who receive 30mL

bupivacaine 0.5% along with 2mL saline as placebo; (intervention)

Category

Treatment - Drugs

4

Description

Patients in group 4 are administered the mentioned solution below in a single shot in the supraclavicular nerve block for upper limb regional anesthesia. Group 4, positive history of opium addictions who receive 30 mL of bupivacaine along with 2 mL sufentanil (10 µg). (intervention)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Dr. Omid Azimaraghi

Street address

Dr Shariati Hospital, North Kargar Ave ,Amirabad

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research-Tehran University of Medical Sciences

Full name of responsible person

Dr. Shahin Akhoondzadeh

Street address

Tehran University of Medical Sciences, Poorsina street ,Keshavarz avenue,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of 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

Chief Resident of Anesthesiology , Dr Shariati Hospital

Full name of responsible person

Dr. Omid Azimaraghi

Position

Chief Resident of Anesthesiology

Other areas of specialty/work

Street address

Dr Shariati Hospital, North Kargar Ave ,Amirabad

City

Tehran

Postal code

Phone

+98 21 2206 6194

Fax

Email

o.azimaraghi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Professor of Anesthesiology at Dr. Shariati Hospital

Full name of responsible person

Dr. Ali Movafegh

Position

Professor of anesthesiology

Other areas of specialty/work

Street address

Dr.Shariati Hospital, North Kargr ave, Amir Abad

City

Tehran

Postal code

Phone

+98 21 8820 2397

Fax

Email

movafegh@sina.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Dr. Shariati Hospital

Full name of responsible person

Dr. Omid Azimaraghi

Position

Chief resident of Anesthesiology

Other areas of specialty/work

Street address

Dr. Shariati Hospital, North Kargar Ave,Amir Abad,

City

Tehran

Postal code

Phone

+98 21 2206 6194

Fax

Email

o.azimaraghi@gmail.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