

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

The Efficacy of Sufentanil-Lidocaine Compound as the Intravenous Regional Anesthetic in Elective Orthopedic Patients

Protocol summary

Study aim

The quality of local anesthetic block with sufentanil in orthopedic patients

Design

This study is a clinical trial in which patients are divided into two groups of 30 each. Patients in group I receive lidocaine with normal saline, and patients in group II receive sufentanil in addition to lidocaine and normal saline.

Settings and conduct

This study will be conducted at Shahid Mohammadi Hospital in Bandar Abbas. Written informed consent was obtained from all patients and after entering the operating room standard monitoring including NIBP (non-invasive blood pressure cuff), pulse oximetry and ECG were attached to them, and all of their baseline vital signs were measured. Afterwards, we placed a double-cuff tourniquet on the arm where was surgery target and a 22-gauge IV angiocatheter was used to inject the medication therein. Then, through holding up the arm for 3 min and with moving around elastic band from fingertip to surgery target, the veins were pumped out. Next, the blood pressure cuff (proximal region) was inflated by a minimal pressure of 100 mmHg higher than systolic pressure (at least 250 mmHg). The elastic band was removed and the lack of blood flow, oximetry pulse signal and radial beats were confirmed. Then, the drug is injected into the target groups.

Participants/Inclusion and exclusion criteria

A randomized, double-blind, controlled clinical trial

Intervention groups

Group 1 will be received 3mg/kg lidocaine 0.5% diluted by normal saline 0.9% (totally 40 ml solution). Group 2, 3mg/kg lidocaine 0.5% diluted by normal saline 0.9% + 4cc sufentanil (totally 40 ml solution).

Main outcome variables

Assessment of sensory and motor block, hemodynamic variables, Assessment of tourniquet pain and side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110313006044N3**

Registration date: **2020-03-10, 1398/12/20**

Registration timing: **prospective**

Last update: **2020-03-10, 1398/12/20**

Update count: **0**

Registration date

2020-03-10, 1398/12/20

Registrant information

Name

Hashem Jarineshin

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3334 5009

Email address

hjarineshin@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of Sufentanil-Lidocaine Compound as the Intravenous Regional Anesthetic in Elective Orthopedic Patients

Public title

The effect of sufentanil on intravenous anesthesia in orthopedic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Candidates aged 18-50 years for- forearm surgery with ASA I,II classes

Exclusion criteria:

Patients who are allergic to sufentanil or topical anesthetic. Patients with a history of liver or kidney disease. Patients who have sickle cell anemia or convulsion. Patients with Raynaud syndrome and neuropathy. Patients who have uncontrolled hypertension and opioid addiction.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample was randomly divided into two groups of 30 patients. Each envelope containing one of the two labels A and B represented one of the intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to eliminate bias from patient's awareness or anesthesia assistant and its possible impact on the outcome of the study, the study will be conducted in a double-blind condition. After receiving written informed consent from patients, local anesthesia was done by giving the same drugs and same volume to the anesthesiologist, then relevant information was recorded in the questionnaire by the anesthesiologist who was not aware of the injection of the drugs. It is obvious that the patient and the anesthesiologist were not aware of the type of drug being administered.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

City

Bandar Abbas

Province

Hormozgan

Postal code

9791991551

Approval date

2015-10-07, 1394/07/15

Ethics committee reference number

HUMS.REC.1394.72

Health conditions studied

1

Description of health condition studied

Forearm surgery

ICD-10 code

S52.9

ICD-10 code description

Unspecified fracture of forearm

Primary outcomes

1

Description

Tourniquet pain

Timepoint

Pain intensity measurement at baseline (before intervention) and 5,10,15 and 20 min after injection

Method of measurement

Patients' severity of pain is based on the Visual Analogues Scale

2

Description

Quality of local anesthesia

Timepoint

During Surgery

Method of measurement

Numerical scale(1-4) of patient satisfaction

Secondary outcomes

1

Description

The evaluation of sensory block

Timepoint

During surgery every 10 minutes

Method of measurement

22-gauge needle on palm in hypothenar (ulna nerve) and thenar (median nerve) eminences and back of the upper arm between thumb and forefinger (radial nerve).

2

Description

The evaluation of motor block

Timepoint

During surgery every 10 minutes

Method of measurement

Observation

3

Description

Side effects such as nausea, vomiting, seizures, hypotension, bradycardia, and itching

Timepoint

During and after surgery

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: The first group 3 mg/kg lidocaine 0.5% diluted with 0.9% normal saline at a total volume of 40 cc.

Category

Treatment - Drugs

2

Description

Intervention group: The second group 3 mg/kg lidocaine 0.5% diluted with 0.9% normal saline + 4 cc sufentanil at a total volume of 40 cc

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Hashem Jarineshin

Street address

Jomhuri Blvd, Shahid Mohammadi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Abdul Azim Nejati Zadeh

Street address

Deputy of research and technology, East Side, Bandar Abbas Hospital, Bandar Abbas

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9791991551

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azimnejate@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bandare-abbas University of Medical Sciences

Proportion provided by this source

50

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Starting the post-access period of the paper was accepted

To whom data/document is available

All researchers

Under which criteria data/document could be used

Using data to complete clinical studies

From where data/document is obtainable

Shahid Mohammadi Hospital

What processes are involved for a request to access data/document

By reviewing the researcher's request and providing sufficient documentation of your research and the reason for using the data, it will be possible.

Comments