

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of axillary perineural injection of dexmedetomidine on hemodynamic changes during the surgical operation and post-operative pain in patients undergoing orthopedic upper extremity surgery

Protocol summary

Summary

The aim of this single-blind clinical trial study was to evaluate of axillary perineural injection of dexmedetomidine on hemodynamic factors during surgery and post-operative pain in patients undergoing upper orthopedic surgery in Shahid Beheshti Hospital, Kashan. Inclusion criteria including patients aged between 18 and 65 years, ASA class I, II, Fracture of the forearm and hands bones, BMI \leq 35 and Patient consent form for study participation and exclusion criteria including Pregnancy, addiction, history of use of agonist or 2α adrenergic antagonist's drugs, coagulation disorders, hypersensitivity to intraoperative drugs and prolonged surgery for more than 120 minutes. Samples were randomly divided into two groups of 30 individuals in intervention and control groups. Patients will receive premedication of 0.05mg/kg Midazolam and 3 μ /kg Fentanyl. The intervention group 100 μ g Dexmedmotidine infusion in the auxiliary and pre- neural region. No injections was used in the control group. Induction was carried out by using 5mg/kg Sodium thiopental and 0.5 mg/kg atracurium. BIS is maintained in the range of 40 to 60 during the operation. At the end of surgery, all patients were reversed by 30 μ /kg Atropine and 50 μ /kg Neostigmine injections. Vital sign changes were recorded prior to the induction and every 15 minutes during the surgery. Postoperative pain was evaluated in recovery and 3, 6, 12 and 24 hours after surgery using VAS scale. Drug intake was recorded in the recovery and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050833860N1**
Registration date: **2017-11-01, 1396/08/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-01, 1396/08/10

Registrant information

Name

Abas Arshia

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 2999

Email address

arshia-a@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of axillary perineural injection of dexmedetomidine on hemodynamic changes during the surgical operation and post-operative pain in patients undergoing orthopedic

upper extremity surgery

Public title

Effect of axillary perineural injection of dexmedetomidine on hemodynamic changes during the surgical operation and post-operative pain in patients undergoing orthopedic upper extremity surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age 18-65, ASA 1, 2, Fracture of the forearm and hands bones, BMI \leq 35 and Patient consent form for study participation. exclusion criteria: Pregnancy, addiction, history of use of agonist or 2 α adrenergic antagonist's drugs, coagulation disorders, hypersensitivity to intraoperative drugs and prolonged surgery for more than 120 minutes.

Age

From **18 years** old to **65 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)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

Kashan

Postal code

Approval date

2017-07-17, 1396/04/26

Ethics committee reference number

IR.KAUMS.MEDNT.REC.16

Health conditions studied

1

Description of health condition studied

Fracture of forearm

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before induction and every 15 minutes during surgery

Method of measurement

Monitoring device

2

Description

Diastolic blood pressure

Timepoint

Before induction and every 15 minutes during surgery

Method of measurement

Monitoring device

3

Description

Heart rate

Timepoint

Before induction and every 15 minutes during surgery

Method of measurement

Monitoring device

4

Description

Postoperative pain

Timepoint

At recovery, 3, 6, 12 and 24 hours after surgery

Method of measurement

visual analogue scale

5

Description

Drug use

Timepoint

In the recovery and the first 24 hours after surgery

Method of measurement

Injection dose based on mg

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 100 µg Dexmedmotidine infusion in the auxiliary and pre- neural region. Induction was carried out by using 5mg/kg Sodium thiopental and 0.5 mg/kg atracurium.

Category

Treatment - Drugs

2

Description

Control group: No injections was used. Induction was carried out by using 5mg/kg Sodium thiopental and 0.5 mg/kg atracurium.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Blvd, Kashan, Iran

City

kashan

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, Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabi

Position

Assistant Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Abass Arshia

Position

Assistant Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arshia

Full name of responsible person

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Position

Assistant Anesthesiologist

Other areas of specialty/work

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Fax

Email

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