Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the preemptive effect of two different doses of dexmedetomidine on changes in blood pressure and heart rate following the use of a tourniquet during a randomized trial of upper extremity orthopedic surgery

Protocol summary

Study aim

Determining the effect of two different doses of 1 and 0.75 (µg/kg) dexmedetomidine on the control of heart rate and blood pressure during the use of tourniquet in upper extremity surgery

Design

Clinical trial with control group, parallel groups, triple-blind, randomized, phase 3 on 90 patients Randomization with random allocation software

Settings and conduct

In Kashani hospital in Isfahan, under EKG monitoring, non-invasive blood pressure and pulse oximetry Dex group 1, 1 (µg/kg) dexmedetomidine induced within 10 minutes, continuation with 0.75 (µg/kg) Dex group 2, 1 (µg/kg) dexmedetomidine induced within 10 minutes, continuation with 1 (µg/kg) Saline group (control), normal saline infusion Identical syringes are used Induction of anesthesia using sodium thiopental 5 (mg/kg), fentanyl 3 (µg/kg), atracurium 0.6 (mg/kg) Maintenance of anesthesia using propofol 0.75 (min/µg/kg) and remifentanil 0.1 (min/µg/kg) Measurement and recording of systolic, diastolic, and mean arterial blood pressure, heart rate, and SpO2 at baseline and at 0, 10, 20, 30, 40, 50, and 60 minutes after inflating the tourniquet and right after emptying it The patient, the person who collects the data, and the statistician are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with ASA (American Society of Anesthesiologists) = 1, aged 18-65 years Exclusion criteria: drug addicts, people with a history of allergy to studied drugs, people with heart, liver and kidney failure, allergy to study drugs, change in anesthesia method, duration of tourniquet less than 60 or more than 150 minutes

Intervention groups

Three groups of 30 patients, dexmedetomidine 1 and 2 and the control group Dex group 1: dose 0.75 (µg/kg) of dexmedetomidine infusion Dex group 2: dose 1 (µg/kg) of dexmedetomidine infusion Control group: normal saline infusion

Main outcome variables

Heart rate; Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090129001615N7**
Registration date: **2023-05-13, 1402/02/23**
Registration timing: **prospective**

Last update: **2023-05-13, 1402/02/23**
Update count: **0**

Registration date

2023-05-13, 1402/02/23

Registrant information

Name
Azim Honarmand
Name of organization / entity
Alzahra hospital
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-05-21, 1402/02/31
Expected recruitment end date
2023-11-21, 1402/08/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the preemptive effect of two different doses of dexmedetomidine on changes in blood pressure and heart rate following the use of a tourniquet during a randomized trial of upper extremity orthopedic surgery

Public title
Investigating the preemptive effect of two different doses of dexmedetomidine on changes in blood pressure and heart rate following the use of a tourniquet during a randomized trial of upper extremity orthopedic surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ASA (American Society of Anesthesiologists) = 1, aged 18-65 years, who are Patients aged 18-65 years Candidates for upper limb orthopedic surgery under tourniquet who undergo general anesthesia
Exclusion criteria:
Addicted people People with a history of allergy to the studied drugs People with heart, liver or kidney failure People with ASA = 2
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
It will be done using Random Allocation software. Patients are placed in three groups of 30, dexmedetomidine 1 and 2 and saline (control) group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The patient and the person collecting the study data are not aware of the study group. The statistician who analyzes the data will also include this requirement.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Soffeh st.
City
Isfahan
Province
Isfehan
Postal code
8174675731
Approval date
2023-03-14, 1401/12/23
Ethics committee reference number
IR.ARI.MUI.REC.1401.334

Health conditions studied

1

Description of health condition studied
Blood pressure
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Heart rate
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Blood pressure
Timepoint
At baseline times (before administration of study drugs) and then at times 0, 10, 20, 30, 40, 50 and 60 minutes after tourniquet inflation and then immediately after deflation
Method of measurement
Sphygmomanometer

2

Description

Heart rate

Timepoint

At baseline times (before administration of study drugs) and then at times 0, 10, 20, 30, 40, 50 and 60 minutes after tourniquet inflation and then immediately after deflation

Method of measurement

Electrocardiogram

3

Description

Oxygen saturation

Timepoint

At baseline times (before administration of study drugs) and then at times 0, 10, 20, 30, 40, 50 and 60 minutes after tourniquet inflation and then immediately after deflation

Method of measurement

Pulse oximeter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group one: In the dexmedetomidine 1 group, 1 (kg/µg) dexmedetomidine is infused within 10 minutes and then continued with a dose of 0.75 (kg/µg) dexmedetomidine infusion during the operation.

Category

Prevention

2

Description

Intervention group two: In the dexmedetomidine group 2, 1 (kg/µg) dexmedetomidine is infused within 10 minutes and then continued with a dose of 1 (kg/µg) dexmedetomidine infusion during the operation.

Category

Prevention

3

Description

Control group: In the control group, normal saline is infused.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Azim Honarmand

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Kashani st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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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

Esfahan University of Medical Sciences

Proportion provided by this source

100

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

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Anesthesiologist and special care specialist
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available